MINISTRY OF HEALTH & FAMILY WELFARE

Government of India

EMPOWERED PROCUREMENT WING (EPW)

INTERNATIONAL COMPETITIVE BIDDING (ICB)

Funding: Domestic Budget

BID DOCUMENT

For

Procurement of Amphotericin –B Injection for Kala-Azar
+
Procurement of Paromomycin IM Injection
+
Procurement of Artesunate Injection Kit

NATIONAL VECTOR BORNE DISEASE CONTROL PROJECT (NVBDCP)

IFB NO.:- RITES/MSM/EPW/NVBDCP/02/2014-15 /DOM

RITES
THE INFRASTRUCTURE PEOPLE

(Procurement Agent)
Materials System Management Division
RITES OFFICE COMPLEX, ANNEX BUILDING, 4TH FLOOR Plot No.144, Sector 44
Gurgaon - 122003, Haryana
INDIA
Fax: 91 (124)/2571659
Tel: 91(124) 2728450,413,428
Email: rites_epw@rediffmail.com

MINISTRY OF HEALTH & FAMILY WELFARE
Empowerment Procurement Wing

Through

RITES Ltd.,
RITES OFFICE COMPLEX-2, ANNEX BUILDING,
4TH FLOOR Plot No.144, Sector 44,
Gurgaon - 122003, Haryana, INDIA
Fax: 91 (124)/2571659
Tel: 91(124) 2728450,413,428

INTERNATIONAL COMPETITIVE BIDDING

FOR

Procurement of Amphotericin –B Injection for Kala-Azar

+

Procurement of Paromomycin IM Injection

+

Procurement of Artesunate Injection Kit

NAME OF THE PROJECT : - National Vector Borne Disease Control Project (NVBDCP)

BID REFERENCE : - RITES/MSM/EPW/NVBDCP/01/2014/Re-bid/DOM

DATE OF COMMENCEMENT OF SALE OF BID DOCUMENT : 6.1.2015 from 10:00 Hrs

DATE AND TIME OF PRE-BID CONFERENCE : 15.1.2015 at 14:00 Hrs

LAST DATE AND TIME FOR RECEIPT OF BID : 24.2.2015 before 14:00 Hrs

TIME AND DATE OF OPENING OF BIDS : 24.2.2015 at 14:15 Hrs

PLACE OF OPENING OF BIDS : RITES Ltd.,
MSM Division, 4th Floor,
Plot No.144, Sector 44,
Gurgaon-122003 (Haryana), India
Fax: 91 (124)/2571659,Tel: 91(124) 2728450,413,428

ADDRESS FOR COMMUNICATION: RITES Ltd.,
MSM Division, 4th Floor,
Plot No.144, Sector 44,
Gurgaon-122003 (Haryana), India
Fax: 91 (124)/2571659,Tel: 91(124) 2728450,413,428

CONTENTS

INVITATION FOR BIDS

Invitation for Bids (IFB)

Country **: India**

Name of Project **: National Vector Borne Disease Control Project (NVBDCP)**

Name of Goods : **Procurement of Amphotericin –B Injection for Kala-Azar ,**

Procurement of Paromomycin IM Injection

Procurement of Artesunate Injection Kit*(Artesunate IP 60mg + 5% Sodium Bicarbonate Injection Amp + Sodium Chloride Solution Amp) along with disposable syringe and needles*

IFB No **: RITES/MSM/EPW/NVBDCP/02/2014/-15/DOM**

1. Ministry of Health & Family Welfare, Govt. of India, intends to utilize part of its domestic budget for eligible payments under the contracts for Procurement of **Amphotericin –B Injection for Kala-Azar , procurement of Paromomycin IM Injection & procurement of Artesunate Injection Kit** against **Schedule I to IX** for which this invitation for bid is issued under National Vector Borne Disease Control Project (NVBDCP).

2. RTES Ltd. (A Govt. of India Enterprise), acting as procurement agent on behalf of Ministry of Health & Family Welfare, Govt. of India now invites sealed bids from eligible bidder for the **procurement of Amphotericin –B Injection for Kala-Azar , procurement of Paromomycin IM Injection & procurement of Artesunate Injection Kit** for the quantities as per Schedule of Requirement to the consignees situated at various locations in India.

3. Bidding will be conducted through the International Competitive Bidding procedures as per the requirements, under GFR 2005 of Ministry of Finance, GOI, as applicable.

4. Interested eligible bidders may obtain further information from RITES Ltd. and inspect the bidding documents at the address given below from 10:00 to 16:00 hrs. (IST) on all working days.

5. A complete set of bidding documents in English may be purchased by interested bidders on the submission of a written application to the address below and upon payment of a nonrefundable fee of **Rs. 5000 or US $ 85.** The method of payment will be by Demand Draft/Pay Order in favour of RITES Ltd., Payable at Gurgaon, India The document may be purchased **6.1.2015** to **24.2.2015 before 14:00 Hrs** from the address mentioned below in S. No. 7. The document can be sent by courier on payment of an extra amount of **Rs 900** for domestic bidder and **US $ 15 (Fifteen)** for overseas bidder if requested by mail.

Bidders can also download the bid document from RITES website "www.rites.com" or "www.eprocure.gov.in". **For downloaded bid document, no fee is required.** The bidders, who have downloaded the bid documents, shall be solely responsible for checking these websites for any addendum/amendment issued subsequently to the bid document and take into consideration the same while preparing and submitting the bids.

6. The bidders or their official representatives are invited to attend a pre bid meeting which will take place on **15.1.2015 at 14:00 hr**s (IST) at the address mentioned below in Sl. No. 7. Please note that non-attendance at the pre-bid conference will not be the cause of disqualification of the bidders. In case the bidder deputes an agent to attend the pre-bid meeting, the Purchaser will be informed in writing by the bidders regarding the appointment of such agent and a copy of the agreement signed between the bidder and the agent (which will include the scope of services provided by such agent and amount payable by the bidder) will be shared with the Purchaser in advance. If this condition is not complied, such agents will not be allowed to attend the meetings and also no queries from such agents will be entertained by the Purchaser. In addition, the bidder will ensure that such agent does not work simultaneously for two or more competing bidders.

7. Bids must be delivered to the address below before **14:00 hrs (IST) on 24.2.2015** . All bids must be accompanied by a bid security as specified in the "Section III – Schedule of Requirements" of the bidding document. Late bids will be rejected. Bids will be opened in the presence of the bidders' representatives who choose to attend at the address below **at 14:15 hrs (IST) on 24.2.2015 .**

Group General Manager- MSM
RITES Ltd.,
RITES Office Complex-2, Annex Building, 4th Floor,
Plot No. 144, Sector 44
Gurgaon - 122003 (Haryana), India
Fax: 91 (124)/2571659
Tel: 91(124) 2728450,413,428
Email: rites_epw@rediffmail.com

SECTION I.

INSTRUCTIONS TO BIDDERS

TABLE OF CLAUSES

A. INTRODUCTION

1. Scope of Bid

1.1 RITES Ltd., RITES office complex-2, Annexe Building, MSM Division 4th Floor, Plot No 144, Sector-44, Gurgaon-122003 (Haryana), India for and on behalf of Ministry of Health & Family Welfare (Govt. of India) (Purchaser) invites bids for the **procurement of Amphotericin –B Injection for Kala-Azar , procurement of Paromomycin IM Injection & procurement of Artesunate Injection Kit (Artesunate IP 60mg + 5% Sodium Bicarbonate Injection Amp + Sodium Chloride Solution Amp) along with disposable syringe and needles.** Detailed description of goods and specifications are given in Schedule Of Requirement and Technical Specification of the bid document respectively. Identification number of this bid is **RITES/MSM/EPW/NVBDCP/02/2014-15/DOM**.

1.2 RITES will be handling the bidding process as well as sign the contracts for this IFB on behalf of the purchaser. The purchaser will exercise all rights and obligations through RITES or any other agency nominated by the purchaser for the purpose of this bid.

1.3 Throughout these bidding documents, the terms "writing" means any handwritten, typewritten, or printed communication, including e-mail and facsimile transmission, and "day" means calendar day. Singular also means plural.

2. Source of Funds

2.1 The Government of India.

3. Fraud and Corruption

3.1 It is the Government of India policy that Bidders/Suppliers/Contractors/Agents under the contracts, observe the highest standard of ethics during the procurement and execution of such Contracts. In pursuance of this policy, the Purchaser :

(a) defines, for the purposes of this provision, the terms set forth below as follows:

(i) "corrupt practice" means the offering, giving, receiving, or soliciting of anything of value to influence the action of a public official in the procurement process or in Contract execution; and

(ii) "fraudulent practice" means any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation;

(iii) "collusive practice" is an arrangement between two or

more parties designed to achieve an improper purpose, including to influence improperly the actions of another party; 1

(iv) "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

(b) will declare a firm ineligible, either indefinitely or for a stated period of time, to be awarded a Contract if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for, or in executing, the contract.

3.2 Furthermore, bidders shall be aware of the provisions stated in Sub-Clauses 6.4 and 23.1 (c) of the General Conditions of Contract.

3.3 In pursuance of the policy defined in ITB Sub-Clause 3.1, the purchaser will cancel the Contract for Goods or works if it at any time determines that corrupt or fraudulent practices were engaged during the procurement or the execution of the Contract.

4. Eligibility

4.1 Except as provided in ITB Sub-Clauses 4.2 & 4.3 this bidding process is open to all qualified manufacturers of the goods or their authorised representative as per Manufacturer's Authorization Form 7 in Section V

4.2 A firm declared ineligible by the Purchaser in accordance with ITB Sub-Clause 3.1(b) shall be ineligible to bid for the contract during the period of time determined by the Purchaser.

4.3 All goods and related services to be supplied under the contract shall have their origin in India or any other country with which India has not banned trade relations.

5. Documents Establishing conformity of Goods and Services to Bidding Documents

5.1 Pursuant to ITB Clause 13, the Bidder shall furnish, as part of its bid, documents establishing, to the Purchaser's satisfaction, the eligibility of the Health Sector Goods and services to be supplied under the Contract.

5.2 The documentary evidence of the eligibility of the Goods and Services shall consist of a statement in the Price Schedule of the country of origin of the Goods and Services offered that shall be confirmed by a certificate of origin issued at the time of shipment.

[1] For the purpose of this sub-paragraph, "party" refers to participants in the procurement process (including public officials) attempting either themselves, or through another person or entity not participating in the procurement or selection process, to simulate competition or to establish bid prices at artificial, non-competitive levels, or are privy to each other's bid prices or other conditions.

5.3 The documentary evidence of conformity of the goods and services to the Bidding Documents may be in the form of literature, drawings, and data and shall consist of:

(a) a detailed description of the essential technical and performance characteristics of the Goods;

(b) an item-by-item commentary on the Purchaser's Technical Specifications demonstrating substantial responsiveness of the Goods and Services to those specifications, or a statement of deviations and exceptions to the provisions of the Technical Specifications;

c) The Goods offered should meet the specified pharmaceuticals standards as stated in the Technical Specifications. If the Goods offered are not included in one of the specified pharmacopoeias (e.g., the case of new drug), the Bidder will provide testing protocols and alternative standards.

5.4 The Goods to be supplied under the Contract shall be registered with the relevant authority in the supplier's and Purchaser's country. A Bidder who has already registered its Goods by the time of bidding should submit a copy of the Registration Certificate with its bid. Otherwise, the successful Bidder, by the time of Contract signing, shall submit to the Purchaser either:

(1) a copy of the Registration Certificate of the Goods for use in the Purchaser's country. .(National Regulatory authority of India (CDSCO).

(2) Copy of documentation indicating that the goods proposed to be supplied under this contract are registered and licensed for use in India by the DCG (I) (Drugs Controller General of India) for imported pharmaceuticals and by the competent authority defined under the Drugs and Cosmetics Act 1940, after appropriate evaluation by centers approved by the DCG (I) (Drugs Controller General of India) for pharmaceuticals produced by indigenous manufacturers.

Note: Bidders are requested to inquire in advance about the registration requirements and procedures in order to avoid any delays due to involvement of various government agencies. Purchaser shall not be responsible for any delay on this account.

5.4.1 The Purchaser shall at all times cooperate with the successful Bidder to facilitate the registration process within the Purchaser's country to the extent possible. The agency and contact person able to provide additional information about the requirements for registration can be obtained from the Website: www.cdsco.nic.in.

5.5 For purposes of the commentary to be furnished pursuant to ITB Clause 5.3 (b) above, the Bidder shall note that standards as well as references to brand names designated by the Purchaser in its Technical Specifications are intended to be descriptive only and not restrictive. The Bidder may substitute alternative standards, brand names, and/or catalogue numbers in its bid, provided that it demonstrates to the Purchaser's satisfaction that the substitutions ensure substantial equivalence to those designated in the Technical Specifications and meet the Pharmacopoeial standards.

6. Qualifications of the Bidder

6.1 The Bidder shall provide documentary evidence to establish to the Purchaser's satisfaction that:

(a) the Bidder has the financial, technical, and production capability necessary to perform the Contract, meets the qualification criteria specified below and has a successful performance history in accordance with criteria specified. If a prequalification process has been undertaken for the Contract, the Bidder shall, as part of its bid, update any information submitted with its application for prequalification.

(b) in the case of a Bidder offering to supply Health Sector Goods, identified in Schedule of requirement, that the Bidder did not manufacture or otherwise produce, the Bidder has been duly authorized by the manufacturer or producer of such Goods to supply the Goods in the Purchaser's country;

(c) in the case of a Bidder who is not doing business within the Purchaser's country (or for other reasons will not itself carry out service/maintenance obligations), the Bidder is or will be (if awarded the Contract) represented by a local service/maintenance provider in the Purchaser's country equipped and able to carry out the Bidder's warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications; and

Along with the bid, the bidder should submit documentary evidence on its qualifications to perform the contract if its bid is accepted as detailed below:

(A) Manufacturer Bidders

(i) that, in the case of a Bidder offering to supply Goods under the Contract which the Bidder manufactures or otherwise produces (using ingredients supplied by primary manufacturers) that the Bidder:

(a) is incorporated in the country of manufacture of the Goods;

(b) has valid license issued by the regulatory authority in the country of manufacture to supply the Goods covered by the

IFB;

(c) has manufactured and marketed the **specific goods** covered by this bidding document for at least two (2) years in the last five (5) years, and for **similar drugs/goods** in the same dosage form for at least three (3) years in the last five (5) years.(preceding two months before the date of bid opening). In support of this, data on past performance should be submitted as per Form 6 in Section V;

(d) i) has received a satisfactory **GMP inspection certificate** in line with the WHO certification scheme on Pharmaceuticals moving in International Commerce from the regulatory authority (RA) in the country of manufacture of the goods [for the factory where the specific pharmaceuticals are manufactured and are being offered for supply] or has been certified by the competent authority of a member country of the Pharmaceuticals Inspection Convention (PIC), and has demonstrated compliance with the above said quality standards during the past one year prior to bid submission;

(ii) **(for syringes and needles)** evidence of compliance [for the factory where the specific goods are manufactured and are being offered for supply] with ISO 13485:2003 by way of accreditation by an independent recognized certification body, and a protocol for testing QUALITY AND SHELF-LIFE of products by the manufacturer.

(e) has a **valid Certificate of Pharmaceuticals Product (COPP)** as recommended by the WHO for each product code offered. COPP should be valid on the date of bid opening.

Note: WHO GMP should be valid on the date of bid opening

(f) provides the evidence that it has the financial, technical and production capability necessary to perform the contract as under:

1. that it has successfully completed at least one (1) contract for similar goods/drugs within the period of last five years (preceding two months before the date of bid opening) for supply of goods against the schedule quoted. Minimum value of completed contract for each schedule should be equal to the quoted value and include comparable products Bidder shall submit list of major supply contracts conducted within the last five years as per Form 6 (Proforma for Performance Statement) in Section V.. Copies of appropriate contracts with proof of execution shall be enclosed.

2. that it has achieved an actual annual production of, similar goods of the quantity specified in schedule of requirement at least equal to the quantities specified against relevant schedules in "Section III schedule of requirements" during any one (1) year of the last five (5) financial years; certified by the Chartered Accountant

3. that it has generated an annual turnover of the value of at least 3 (three) times of the quoted value against each schedule, during any one of the last three financial years, to qualify for a schedule. If the bidder quotes for more than one Schedule, the above criteria shall be cumulative. The turnover is to be supported by audited financial statements of accounts (including balance sheet, profit and loss account, auditor's reports, and IT returns) for the past three fiscal years duly certified by the auditor of the Company.

4. provides proof of experience with and knowledge of modes of packing, distribution and transportation of pharmaceuticals, similar to those subject to bidding under logistical and climatic conditions similar to the ones in the purchaser's country. It should provide names of clients/countries to which the bidder has supplied (including packaged, distributed, and transported) products worth at least equivalent to US $ 50,000 or more within the past five years.

   In addition, bidders should submit with their bids the source and suitability of the Active Pharmaceuticals Ingredient (API) intended for use in the manufacture of the specified products, including a written commitment from the Active Pharmaceuticals Ingredient (API) manufacturer that they have the technical capability & sufficient capacity to supply the full requirement of the schedules for which the bidder has submitted bids.

5. When offering their bid for more than one schedule, the bidder must provide evidence that it meets or exceeds the sum of all the individual requirements for the schedules being applied for in regard to

(I) Actual annual production (sub-clause (f) (2) above) and
(II) Actual annual turnover (sub-clause (f) (3) above).

Hence, if the bidder quotes for more than one schedule, the above criteria shall be cumulative.

In case a bidder fails to fully meet any of these criteria, it will be qualified only for those schedules for which the bidder meets the above requirements and the combination of schedules to be awarded to such bidder will be decided based on the lowest cost of the combination to the Purchaser. The decision of the buyer in this regard shall be final and binding on the bidder.

B) Non Manufacturer Bidder

a) In the case of a bidder offering to supply goods under the contract that the bidder does not manufacture or otherwise produce:

(i) that the bidder should be duly authorized (as per authorization Form 7 in Section V) by the manufacturer of the goods who meets the criteria under (A) above. Information as asked for manufacturer shall be submitted with the bid,

(ii)that it has successfully completed at least one (1) similar contract within the period of last five years (preceding two months before the date of bid opening) for supply of goods against the schedule quoted. Minimum value of completed contract for each schedule should be at least 50% of the quoted value and that include comparable products. Bidder shall submit list of major supply contracts conducted within the last five years as per form 6 (Proforma for Performance Statement) in Section V. Copies of appropriate contracts with proof of execution shall be enclosed.

(iii) that it has generated an annual turnover (against each schedule) of at least equal to the quoted value, during any one of the last three financial years, to qualify for a schedule. If the bidder quotes for more than one Schedule, the above criteria shall be cumulative. The turnover is to be supported by audited financial statements of accounts (including balance sheet, profit and loss account, auditor's reports, and IT returns) for the past three fiscal years duly certified by the auditor of the Company.

If the bidder quotes for more than one Schedule, the above criteria shall be cumulative.

(**NOTE:** In case any bidder is lowest evaluated & responsive in more than one schedule but fails to meet the cumulative requirement of turn over for those schedules, it will be qualified only for those schedules for which the bidder or the manufacturer meets the above requirements and combination of the schedules to be awarded to such bidders will be decided based on the lowest cost of the combination to the Purchaser.

The decision of the buyer shall be final and binding on the bidder.

(C) For both (A) and (B)

a) Copies of original documents defining the constitution or legal status, place of registration, and principal place of business; written power of attorney of the signatory of the Bid to commit the Bidder;

b) **The bidder (including their manufacturer) shall disclose instances of previous past performance that may have resulted in adverse actions** taken against the bidder and the manufacturers whose products are being offered by the bidder, in the last two years. Such adverse actions taken against the bidder or manufacturer may be treated as unsatisfactory performance history while deciding the award of contract. If no instance of previous past performance has resulted into adverse actions this should be clearly indicated in the bidder's bid

(i) The supplier shall not supply items manufactured from any of its production units which is banned by DCGI. In addition, any alert issued by any Regulatory authority shall be immediately brought to the notice of the Purchaser and further supply shall be made only after obtaining clearance from the purchaser/client.

c) The bidder shall provide an undertaking that
   i. the proprietor/promoter/director of the firm, its employee, partner or representative is not convicted by a court of law following prosecution for offence involving moral turpitude in relation to business dealings including malpractices such as bribery, corruption, fraud, substitution of bids, interpolation, misrepresentation, evasion, or habitual default in payment of tax levied by law etc.
   ii. the firm do not employ a government servant, who has been dismissed or removed on account of corruption.

d) Bidder quoting against this bid will have to invariably disclose the name of the manufacturer of the individual item along with the quantity he proposes to obtain from them. In case any bidder indicates only the list of the manufacturer without indicating the quantity he proposes to obtain from that manufacturer, the bids are liable to be considered non-responsive.

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Note-

1. An agent submitting a bid in its own name will be treated as a non-manufacturer bidder.

2. The bidder must complete the Checklist given in Section V as Form No.13 and submit it along with the Bid.

3. The bidder should Serial no. all the documents of his bid, provide a summery table & sign/initial all the pages.

4. The bidder should furnish details of two persons that RITES may contact for requests for clarification during bid evaluation:

Name		
Telephone No (direct)		
Email address		

5. The bidder should furnish the Bank details from where the Bank Guarantee has been issued along with Phone, fax numbers and email Ids. For Banks from outside India the details of the correspondent Bank in India.

6. Bidder should furnish Authority to the Purchaser to seek references from the Bidder's bankers.

The Bidder shall also submit the following additional information:

a. A copy of its manufacturing license with product number and date and installed manufacturing capacity.

b. Details of on-site quality control laboratory facilities and services and range of tests conducted should be submitted. The manufacturer should have a Quality Management System to the satisfaction of the purchaser.

c. Copies of its audited financial statements for the past three fiscal years.

d. A copy of the achieved annual production certified by Chartered Accountant.

e. List of major supply contracts conducted (Completed & ongoing) with in last five years as per form 6 in Section V.

f. Capacity and Quality certification form in the specified format (5b of Section V in sample forms) issued by relevant controlling authority.

g. If the products offered are of foreign origin, the bidder shall be required to submit Import Licence (Standard Form 10 as per Drugs and Cosmetic Act) issued in the name of bidder for the offered drugs issued by Licensing Authority as per Drugs

and Cosmetics Act 2005.

h. List of products being manufactured by the bidder with product registration/ license number and date.

7. One Bid per Bidder

7.1 A firm shall submit only one bid in the same bidding process, either individually as a bidder or as a partner of a joint venture. No firm can be a subcontractor while submitting a bid individually or as a partner of a joint venture in the same bidding process. A Subcontractor in any bid may participate in more than one bids, but only in that capacity. A firm that submits a bid individually or as a joint venture partner, and also participates in any capacity in another bid, will cause all the bids in which the firm has participated to be disqualified.

8. Cost of Bidding

8.1 The Bidder shall bear all costs associated with the preparation and submission of its bid, and the Purchaser will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bidding process.

B. THE BIDDING DOCUMENTS

9. Content of Bidding Documents

9.1 The Bidding Documents are those stated below and should be read in conjunction with any addendum issued in accordance with ITB Clause 11.

Section I.	Instructions to Bidders (ITB)
Section II.	General Conditions of Contract (GCC)
Section III.	Schedule of Requirements
Section IV.	Technical Specifications
Section V.	Sample Forms (including Contract Agreement)

9.2 The "Invitation for Bids" does not form part of the Bidding Documents and is included as a reference only. In case of discrepancies between the Invitation for Bid and the Bidding Documents listed in 9.1 above, said Bidding Documents will take precedence.

10. Clarification of Bidding Documents

10.1 A prospective Bidder requiring any clarification of the Bidding Documents shall contact the Purchaser in writing or by cable (for these ITB, the term "cable" is deemed to include electronic mail, telex, or facsimile) at the Purchaser's address indicated in the clause 21.2 (b) of ITB. The Purchaser will respond in writing to any request for clarification received no later than fourteen (14) calendar days prior to the deadline of submission of bids. Copies of the Purchaser's response shall be sent to all Bidders in ICB including a description of the inquiry but without identifying its source.

Pre Bid meeting: - The bidder or his official representatives is invited to attend a pre bid meeting which will take place as per details given below: -
Date:- **15.1.2015**
Time: **14:00 hrs (IST)**
Venue:
RITES Ltd., RITES Office Complex-2,
Annexe Building, MSM Division 4th
floor, Plot No-144, Sec-44,
Gurgaon-122003(Haryana),

Non-attendance at the pre bid meeting will not be a cause for disqualification of a bidder. Interested bidders should only depute their staff to attend the pre-bid meeting.

11. Amendment of Bidding Documents

11.1 At any time prior to the deadline for submission of bids, the Purchaser may amend the Bidding Documents by issuing Addenda.

11.2 Any addendum thus issued shall be part of the Bidding Documents pursuant to ITB Sub-Clause 9.1 and shall be communicated in writing to all purchasers of the Bidding Documents and will be binding on them. Bidders are required to immediately acknowledge receipt of any such amendment, and it will be assumed that the information contained in the amendment will have been taken into account by the Bidder in its bid.

11.3 To give prospective Bidders reasonable time in which to take the amendment into account in preparing their bids, the Purchaser shall extend, at its discretion, the deadline for submission of bids, in which case, the Purchaser will notify all Bidders by cable confirmed in writing of the extended deadline.

C. PREPARATION OF BIDS

12. Language of Bid

12.1 The bid, as well as all correspondence and documents relating to the bid exchanged by the Bidder and the Purchaser, shall be written in English language. Supporting documents and printed literature furnished by the Bidder may be in another language provided they are accompanied by an accurate translation of the relevant passages in the English language.

13. Documents Constituting the Bid

13.1 The bid submitted by the Bidder shall comprise the following:

a) Documentary evidence establishing to the purchaser's satisfaction and in accordance with ITB clause 6 that the Bidder/Manufacturer is qualified to perform the contract if its bid is accepted. In the case where prequalification of the bidders has been undertaken, and pursuant to ITB 6 the Bidder must provide evidence on any changes in the information submitted as the basis for prequalification, or if

there has been no change at all in said information, a statement to this effect;

(b) Duly filled-in Form of Bid and Price Schedule, in accordance with the forms indicated in Section V;

(c) Original form of bid security in accordance with the provisions of ITB Sub-Clause 18.3 (Bid Security);

d) Written power of attorney authorizing the signatory of the bid to commit the Bidder;

For Indian Bidders: Power of Attorney should be submitted on non judicial stamp paper and the person signing the Power of Attorney should sign by hand.
Stamped, electronic or scanned signature is not acceptable and such bid will be considered non-responsive.

For foreign bidders: Power of attorney should be submitted on a paper similar to non judicial stamp paper, if any, as per the law of the country of the bidder. If there is no such legal paper available in the country of the bidder, the same should be confirmed under the stamp and signature by hand of the person signing the power of attorney. In such a case Power of attorney can be submitted on plain paper duly signed by hand. Stamped, electronic or scanned signature is not acceptable and such bid will be considered non-responsive.

e) 'Integrity Pact' in accordance with ITB Clause 43.

f) Certification of incorporation of the bidder and manufacturer

g) Bidders who are not primary manufacturers should provide evidence that their product conforms to the quality standards of the primary manufacturer and they have the capacity to supply the specified quantities.

h) A "primary manufacturer" is defined as a company that performs all the manufacturing and processing operations needed to produce pharmaceuticals or vaccines in their appropriate dosage forms, including processing, blending, formulating, filling, packing, labeling and quality testing. Bids may be submitted by an authorized agent for and on behalf of the primary manufacturer provided the bid is accompanied by a duly notarized letter of authority from the primary manufacturer authorizing the designated agent to bid solely for and on behalf of the primary manufacturer. Merchant exporters, pre-packers, shippers and traders are not classified as primary manufacturers and bids from them

will not be accepted.

i) The bidder shall furnish a certificate from the competent Regulatory Authority (RA) that the manufacturers is licensed to manufacture the goods offered.

j) The following details shall be provided by Indian Bidder:

1. Name, address, PAN and Income Tax details (ward/circle where they are being assessed) of the directors of the bidding company.

2. Company's PAN and Income Tax details and ward/circle where they are being assessed.

k) Registration details of the company under VAT, local and central sales Tax and other laws as may be applicable and also sales tax /VAT clearance certificate.

14. Bid Form

The Bidder shall complete the Bid Form and the Price Schedule furnished in the Bidding Documents, indicating the Goods to be supplied, a brief description of the Goods, their country of origin, and unit prices. (All details of the price components like taxes, duties etc. may also be indicated).

The bidder shall furnish in the bid form (form no. 1, Section V) information regarding commissions or gratuities if any, paid or to be paid to agents relating to this bid and to the execution of the contract if the bidder is awarded the contract.

15. Bid Prices

15.1 The Bidder shall indicate on the Price Schedule, the unit price of each item, it proposes to supply under the Contract. The bidders are allowed the option to submit the bids for any one or more schedules specified in the 'Schedule of Requirements

15.2 The bidder shall quote the prices on "Door Delivery Basis"(DDP consignee End as per INCOTERMS) to all consignees. The list of probable consignees is attached in schedule of requirement. However the list of consignees is the tentative list. The purchaser reserves the right to change any consignee at the time of placement of order.

15.3 The rate quoted should be both in words and figures. No figure or word should, be over written. Correction if any should be rewritten under the full signature of the person signing the tender.

15.4 The rate of Excise Duty and quantum of Excise should be shown distinctly. Similarly, Sales Tax/VAT, if any, where legally leviable and intended to be claimed extra should be shown distinctly as percentage along with the price quoted, separately. Where this is not done, no claim for excise duty and or Sales Tax/VAT will be

admitted at any later stage on any ground.

15.5 (a) **Indigenous goods**:- Prices indicated on the Price Schedule shall be entered separately in the following manner:

(i) the price of the Goods quoted EXW (ex works, ex factory, ex warehouse, ex showroom, or off-the-shelf, as applicable), including custom, excise and sales tax and other duties and taxes already paid or payable: on the components and raw material used in producing or manufacturing the Goods quoted ex works or ex factory;

(ii) the rate and quantum of Excise duty and Sales Tax/VAT if any that will be payable on the Goods if the Contract is awarded.

(iii) the price for inland transportation and other local costs incidental to delivery of the Goods to their final destination, The final destination is specified in Schedule of Requirements (Section III)

(b) Already Imported goods: - Offers for Imported origin goods shall clearly indicate firm, "All inclusive lump sum price" calculated in equivalent Indian Rupees and giving break up of as CIF (Indian Port), custom charges and other charges including inland transportation etc. The all inclusive lump sum price shall take care of impact of foreign exchange rate fluctuations etc., and accordingly arrive at the all inclusive lump sum price in equivalent Indian Rupees and this shall be the ceiling amount payable.

The terms EXW, CIF etc., shall be governed by the rules prescribed in the current edition of *Incoterms 2010* published by the International Chamber of Commerce, Paris.

15.6 The prices quoted by the bidder should be on firm and fixed basis during the performance of the contract. A bid submitted with adjustable price quotation will be treated as non responsive and will be rejected pursuant to ITB clause 28.

15.7 The bidder's separation of price components in accordance with clause above will be solely for the purpose of facilitating the comparison of bids by the purchaser and will not in any way limit the purchaser's right to contract on any of the terms offered.

15.8 The purchaser shall not be liable to any claim on account of fresh imposition and/or increase of Excise Duty, Customs duty, Sales Tax on raw materials and/or components used directly in the manufacture of the contracted stores taking place during the pendency of the contract.

15.9 Statutory variation in taxes and duties on finished product quoted extra will be on purchaser's account during currency of contract.

16. Currencies of Bid

16.1 Prices shall be quoted in Indian Rupess or US Dollars. For domestic goods and services, prices shall be quoted in Indian Rupees only. Commission for Indian Agent as declared in the bid, if any and if payable shall be indicated in the price schedule form (2.b of Section V) and will be in Indian Rupees only..

17. Period of Validity of Bids

17.1 Bids shall remain valid for the period of **150 days** after the date of bid submission specified in ITB Clause 22. A bid valid for a shorter period shall be rejected by the Purchaser as non-responsive.

17.2 In exceptional circumstances, prior to expiry of the original bid validity period, the Purchaser may request that the Bidders extend the period of validity of the original bid for a specified additional period. The request and the responses thereto shall be made in writing. A Bidder may refuse the request without forfeiting its bid security.

18. Bid Security

18.1 The Bidder shall furnish, as part of its bid, a bid security against each schedule in fixed amount as specified in Section –III, Schedule of Requirement. The amount of bid security against each schedule(s) should be in fixed amount as specified in the Schedule of Requirements.

If the bidder is submitting bid for more than one schedule, the amount of the bid security shall be the sum of bid securities required for the respective schedules. The bidder has the option to submit individual bid security instrument for different schedules.

If the amount of bid security furnished is less than the required for total quoted schedules by the bidders, and then Bid security will be considered valid only for the quoted schedules (in serial order of the Schedule of Requirement). The later schedule(s) for which Bid security fall short, will be treated as non-responsive.

18.2 The bid security shall remain valid for a period of **45 days** beyond the validity period for the bid and beyond any extension subsequently requested under Sub-clause 17.1.

18.3 The bid security shall be denominated in Indian Rupees or in US dollar , and shall be, at the Bidder's option, in one of the following forms:

(a) a crossed demand draft or a pay order drawn in favour of the Purchaser;
(b) a (bank) guarantee issued by a nationalized/scheduled bank in India. The format of the (bank) guarantee shall be in accordance with the form of bid security included in Section V.

(c) In the case of Bank Guarantee furnished from banks outside India, it should be authenticated and countersigned by any Nationalised or Scheduled bank in India.

18.4 Any bid not accompanied by an acceptable bid security shall be rejected by the Purchaser as non-responsive, except when exemption is permitted as per rules of GOI, as on date of bid opening.

18.5 The bid securities of unsuccessful Bidders will be returned as promptly as possible.

18.6 The bid security of the successful Bidder will be returned when the Bidder has signed the Agreement and furnished the required performance security.

18.7 The bid security may be forfeited:

(a) if the Bidder withdraws its bid, except as provided in ITB Sub-Clauses 17.2 and 24.3; or

(b) in the case of a successful bidder, if the Bidder fails within the specified time limit to:

(i) sign the contract, or

(ii) furnish the required performance security, or

(iii) In case of any false, incorrect or misleading information provided in the bid.

19. Alternative Proposals by Bidders

Alternative bids shall not be accepted. The bidder should not submit more than one bid for any Schedule.

20. Format and Signing of Bid

20.1 The Bidder shall prepare one original and one copy of the bid**,** clearly marking each one as "ORIGINAL BID" and "COPY OF BID," as appropriate. In the event of any discrepancy between them, the original shall govern.

20.2 The original and all copies of the bid, each consisting of the documents listed in ITB Sub-Clause 13.1, shall be typed or written in indelible ink and shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the Contract. . Stamped, electronic or scanned signature is not acceptable and such bid will be considered non-responsive. The later authorization shall be indicated by written power of attorney, which pursuant to ITB Sub-Clause 13.1 (c) shall accompany the bid.

20.3 Any interlineations, erasures, or overwriting to correct errors made by the Bidder should be initialled by the person or persons signing

the bid.

20.4 The Bidder shall furnish in the Bid Form (a sample of which is provided in the Sample Forms Section of the Bidding Documents) information regarding commissions or gratuities, if any, paid or to be paid to agents relating to this bid and to the execution of the Contract if the Bidder is awarded the Contract

D. Submission of Bids

21. Sealing and Marking of Bids

21.1 The Bidder shall enclose the original and each copy of the bid in separate sealed envelopes, duly marking the envelopes as "ORIGINAL" and "COPY." The envelopes containing the original and copies shall then be enclosed in another envelope. Bidders shall not have the option of submitting their bids electronically. **1 soft copy in CD in sealed envelope should be submitted with the 'ORIGINAL' bid.**

21.2 The inner and outer envelopes shall:

(a) bear the name and address of the Bidder;

(b) be addressed to the Purchaser at the address given below

Group General Manager/MSM
RITES Ltd., RITES Office Complex-2,
Annexe Building, MSM Division 4th floor, Plot No-144, Sec-44,Gurgaon-122003(Haryana),
India

(c) The inner and outer envelopes shall bear the following additional identification marks:

Invitation for Bids Title:
Invitation for Bids Number:
Schedule Number:
Time & Date of Submission of Bids:
Name of the Goods

(d) bear a statement "DO NOT OPEN BEFORE **24.2.2015** at 14:15 hrs " to be completed with the time and date specified in the ITB clause 22.1.

21.3 If the outer envelope is not sealed and marked as required by ITB Sub-Clause 21.2, the Purchaser will assume no responsibility for the misplacement or premature opening of the bid.

22. Deadline for Submission of Bids

22.1 Bids must be received by the Purchaser at the address specified in the ITB Sub-Clause 21.2 (b) no later than the time and date specified below:-

Bids must be delivered before 14:00 Hrs. on **24.2.2015**. Late bids will be rejected.

"In event of the specified date for the submission of Bids being declared a holiday for the Purchaser, the Bids will be received up to the appointed time on the next working day".

22.2 The Purchaser may, at its discretion, extend the deadline for the submission of bids by amending the Bidding Documents in accordance with ITB Sub-Clause 11.3, in which case all rights and obligations of the Purchaser and Bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

23. Late Bids

23.1 Any bid received by the Purchaser after the deadline for submission of bids prescribed by the Purchaser in the ITB Clause 22 will be rejected and returned unopened to the Bidder. See ITB Sub-Clause 22.1 for the deadline for bid submission.

24. Modification and Withdrawal of Bids

24.1 The Bidder may modify or withdraw its bid after submission, provided that written notice of the modification, or withdrawal of the bids duly signed by an authorized representative, is received by the Purchaser prior to the deadline prescribed for submission of bids.

Note: No bid may be modified subsequent to the deadline for submission of bid.

24.2 The Bidder's modification shall be prepared, sealed, marked, and dispatched as follows:

(a) The Bidder shall provide an original and the number of copies specified in the ITB clause 20.1 of any modifications to its bid, clearly identified as such, in two inner envelopes duly marked "BID MODIFICATION-ORIGINAL" and "BID MODIFICATION-COPY." The inner envelopes shall be sealed in an outer envelope, which shall be duly marked "BID MODIFICATION." The required number of copies of bid modifications is the same as the number of copies of the original bid specified above in the data for ITB Sub-Clause 20.1.

(b) Other provisions concerning the marking and dispatch of bid modifications shall be in accordance with ITB Sub-Clauses 21.2 and 21.3.

24.3 A Bidder wishing to withdraw its bid shall notify the Purchaser in writing prior to the deadline prescribed for bid submission. A withdrawal notice shall be received prior to the deadline for submission of bids. The notice of withdrawal shall:

(a) be addressed to the Purchaser at the address named in the ITB clause 21.2 (b)

(b) bear the specific identification of the bidding process (Contract

name), the IFB title and IFB number, and the words "BID WITHDRAWAL NOTICE," and

(c) be accompanied by a written power of attorney authorizing the signatory of the withdrawal notice to withdraw the bid.

24.4 Bids requested to be withdrawn in accordance with ITB Sub-Clause 24.3, shall be returned unopened to the Bidders.

24.5 No bid may be withdrawn in the interval between the bid submission deadline and the expiration of the bid validity period specified in ITB Clause 17. Withdrawal of a bid during this interval may result in the forfeiture of the Bidder's bid security, pursuant to ITB Sub-Clause 18.7.

E. OPENING AND EVALUATION OF BIDS

25. Bid Opening

25.1 The Purchaser will open all bids, including withdrawal notices and modifications, in public, in the presence of Bidders' representatives who choose to attend, at 14.:15 hrs, on the date, and at the place specified below:

Time, date, and place for bid opening are: **14:15 hrs** (Indian Standard Time) on **24.2.2015** at the following address:

RITES Ltd., RITES Office Complex-2,
Annexe Building, MSM Division, 4th floor,
Plot No-144, Sec-44,
Gurgaon.-122003(Haryana),
India.

"In the event of the specified date of the bid opening being declared a holiday for the Purchaser, the bids shall be opened at the appointed time and Location on the next working day."

In case the bidder uses an agent in any capacity, the Purchaser will be informed in writing by the bidders regarding the appointment of such agent and a copy of the agreement signed between the bidder and the agent (which will include the scope of services provided by such agent and amount payable by the bidder) will be shared with the Purchaser in advance. The agreement should be legally binding with the clear understanding that the Bidder will be held responsible for unlawful actions (viz. fraudulent representation, bribing or collusion) of the agent. If this condition is not complied, such agents will not be allowed to attend the meetings and also no queries from such agents will be entertained by the Purchaser. In addition, the bidder will ensure that such agent should not work simultaneously for two or more competing bidders.

Bidders' representatives shall sign a register as proof of their

attendance. All bids must be accompanied by a bid security as specified in Section –III, Schedule of Requirements.

25.2 Envelopes marked "WITHDRAWAL" shall be read out and the envelope with the corresponding bid shall not be opened but returned to the Bidder. No bid withdrawal shall be permitted unless the corresponding withdrawal notice is read out at bid opening. Envelopes marked "MODIFICATION" shall be read out and opened with the corresponding bid.

25.3 Bids shall be opened one at a time, reading out: the name of the Bidder and whether there is a modification; the bid price of each item or lot, as the case may be, including discounts the presence or absence of a bid security, if required; the presence or absence of requisite powers of attorney; and any other such details as the Purchaser may consider appropriate. No bid shall be rejected at bid opening except for late bids pursuant to Sub-Clause 23.1.

25.4 Bids (and modifications sent pursuant to ITB Sub-Clause 24.2) that are not opened and read out at bid opening shall not be considered further for evaluation, irrespective of the circumstances.

25.5 The Purchaser will prepare minutes of the bid opening at the end of the opening session, including, as a minimum: the name of the Bidder and whether there was a withdrawal or modification; the bid price; including any discounts or alternatives offered if permitted in the Bid Data Sheet; the presence or absence of a bid security; the presence or absence of requisite powers of attorney.

25.6 The Bidder's representatives who are present shall be requested to sign the minutes. The omission of a Bidder's signature on the minutes shall not invalidate the content and effect of the minutes. The minutes should be distributed to all Bidders who request them.

26. Clarification of Bids

26.1 During evaluation of the bids, the Purchaser may, at its discretion, ask the Bidder for a clarification of its bid. The request for clarification and the response shall be in writing, and no change in the prices or substance of the bid shall be sought, offered, or permitted, except to correct arithmetic errors identified by the Purchaser in the evaluation of the bids, in accordance with ITB Sub-Clause 29.1.

27.Confidentiality

27.1 Information relating to the examination, clarification, evaluation, and comparison of bids, and recommendations for the award of a Contract shall not be disclosed to bidders or any other persons not officially concerned with such process until the notification of Contract award is made to all Bidders.

27.2 Any effort by the bidder to influence the Purchaser in the Purchaser's bid evaluation, bid comparison, or contract award decisions may

result in the rejection of the Bidder's bid.

27.3 From the time of bid opening to the time of Contract award, if any Bidder wishes to contact the Purchaser on any matter related to its bid, it should do so in writing.

28. Examination of Bids and Determination of Responsiveness

28.1 The Purchaser will examine the bids to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed, and whether the bids are generally in order.

28.2 The Purchaser may waive any minor informality, nonconformity, or irregularity in a bid that does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any Bidder. Wherever applicable, the purchaser will ensure that each bid is from a prequalified bidder.

28.3 Prior to the detailed evaluation, pursuant to ITB Clause 30, the Purchaser will determine whether each bid is of acceptable quality, is complete, and is substantially responsive to the Bidding Documents. For purposes of this determination, a substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the Bidding Documents without material deviations, exceptions, objections, conditionality's, or reservations. A material deviation, exception, objection, conditionality, or reservation is one: (i) that limits in any substantial way the scope, quality, or performance of the Goods and related Services; (ii) that limits, in any substantial way that is inconsistent with the Bidding Documents, the Purchaser's rights or the successful Bidder's obligations under the Contract; and (iii) that the acceptance of which would unfairly affect the competitive position of other Bidders who have submitted substantially responsive bids.

The following clauses are the critical provisions, deviations from or objections or reservations to which, may be treated as material deviations:

- Non submission of Bid Form
- Bid Validity (ITB Clause 17)
- Bid Security (ITB Clause 18);
- Validity of Bid Security (ITB Clause 18.2)
- Performance Security (GCC Clause 8);
- Delivery Terms (GCC Clause 11 & Schedule of Requirements)
- Warranty (GCC Clause 15);
- Payment terms (GCC Clause 16)
- Force Majeure (GCC Clause 24);
- Limitation of liability (GCC Clause 28)
- Applicable Law (GCC Clause 30);
- Taxes and Duties (GCC Clause 32);
- Technical Specification (As per Section IV)

- Delivery Period (Schedule of Requirements)

Above list is non-exhaustive.

28.3 If a bid is not substantially responsive, it will be rejected by the Purchaser and may not subsequently be made responsive by the Bidder by correction of the nonconformity. The Purchaser's determination of a bid's responsiveness is to be based on the contents of the bid itself without recourse to extrinsic evidence.

29. Correction of Errors

29.1 Arithmetical errors will be rectified as follows. If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity , the unit or subtotal price shall prevail. If there is a discrepancy between the subtotals and the total price, the total price shall be corrected. If there is a discrepancy between words and figures, the amount in words will prevail. If a Bidder does not accept the correction of errors, its bid will be rejected and its bid security may be forfeited.

30. Conversion to Single Currency

30.1 To facilitate evaluation and comparison, the Purchaser will convert all bid prices expressed in the various currencies in which they are payable to the currency of the Purchaser's country(INR) at the selling exchange rate established for similar transactions by the SBI, New Delhi as on date of bid opening.

31. Evaluation and Comparison of Bids

31.1 The Purchaser will evaluate and compare the bids that have been determined to be substantially responsive, pursuant to ITB Clause 28.

31.2 The Purchaser's evaluation of a bid will take into account the total unit cost of the item at the consignee's destination inclusive of all duties & taxes.

31.3 The contract shall be awarded only to the lowest evaluated bidder for each schedule who is substantially responsive, offer competitive rates, and meet the qualification requirements stipulated in the bidding documents.

31.4 Bidder may bid for one or more schedules. Bids will be evaluated for each schedule separately and the contract will comprise the schedules(s) awarded to the successful bidder. Bidders must quote for the entire quantity of each schedule. Bidders who do not quote for full quantity of the schedule will be treated as non-responsive.

31.5 a) Deviations in the delivery schedule and Payment Schedule are not permitted.

31.6 In exercising of the powers conferred in Section 11 of the Micro, Small and Medium Enterprises Development (MSMED) Act 2006, the Government has notified a new Public Procurement Policy for Micro & Small Enterprises effective from 1st April 2012.

In accordance to the above notification the participating Micro and Small Enterprises (MSEs) in a Bid, quoting price within the band of L1+15% would be allowed to supply a portion of the requirement by bringing down their price to the L1 price, in a situation where L1 price is from someone other than an MSE. Such MSEs would be allowed to supply up to 20% of the total Bid value. In case there are more than one such eligible MSE, the 20% supply will be shared equally. Out of 20% of the quantity earmarked for supply from MSEs, 4% quantity is earmarked for procurement from MSEs owned by SC/ST entrepreneurs. However, in the event of failure of such MSEs to participate in the Bid process or meet the Bid requirements and the L1 price, the 4% quantity earmarked for MSEs owned by SC/ST entrepreneurs will be met from other participating SMEs.

The MSEs participating in the bid shall enclose with their Bid a copy of their valid registration certificate with District Industries Centres or Khadi and Village Industries Commission or Coir Board or NSIC or any other body specified by Ministry of Micro and Small enterprices in support of their being an MSE, failing which their offer will be liable to be ignored.

F. AWARD OF CONTRACT

32. Post qualification

32.1 The Purchaser will determine to its satisfaction whether the Bidder that is selected as having submitted the lowest evaluated responsive bid is qualified to perform the Contract satisfactorily, in accordance with the criteria listed in ITB Sub-Clause 6.1.

If a prequalification process was undertaken for the Contract(s) for which these Bidding Documents were issued, the Purchaser will determine in the manner described above that no material changes have occurred after the prequalification that negatively affect the ability of the Bidder that has submitted the lowest evaluated bid to perform the Contract.

Before the award of the contract the Purchaser may inspect the site of the responsive bidders as well as the site of manufacturers of the goods being supplied to assess the supplier's/manufacturer's capacity to successfully perform the contract as per the terms and conditions specified in the bid document. The inspection check-list is attached with this bidding document at Form 14.

32.2 The determination will evaluate the Bidder's financial, technical, and production capabilities. It will be based on an examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, pursuant to ITB Sub-Clause 6.1, as well as other information the Purchaser deems necessary and appropriate.

32.3 An affirmative post qualification determination will be a prerequisite for award of the contract to the lowest evaluated Bidder. A negative determination will result in rejection of the Bidder's bid, in which event the Purchaser will proceed to the next-lowest evaluated Bidder to make a similar determination of that Bidder's capabilities to perform satisfactorily.

33. Award Criteria

33.1 Pursuant to ITB Clauses 31 and 36, the Purchaser will award the Contract to the Bidder whose bid has been determined to be substantially responsive and has been determined to be the lowest evaluated bid, provided further that the Bidder is determined to be qualified to perform the Contract satisfactorily, pursuant to ITB Clause 31.

34. Purchaser's Right to Accept Any Bid and to Reject Any or All Bids

34.1 The Purchaser reserves the right to accept or reject any bid, or to annul the bidding process and reject all bids at any time prior to contract award, without thereby incurring any liability to the affected Bidder or Bidders. No reason for such action of Purchaser shall be given.

35. Purchaser's right to vary quantities

35.1 The Purchaser reserves the right to increase or decrease the quantity of goods by 20% at time of award or during the currency of contract, the quantity of goods and services beyond that originally specified in the Schedule of Requirements, shall be without any change in unit price or other terms & conditions**.** Delivery period for additional quantity under tolerance clause shall be on pro-rata basis of original delivery.

36. Notification of Award

36.1 Prior to the expiration of the period of bid validity, the Purchaser will notify the successful Bidder in writing by registered letter or by fax/e-mail, to be subsequently confirmed in writing by registered letter, that its bid has been accepted for award of contract.

36.2 Upon the successful Bidder's furnishing of the signed Contract Form and performance security pursuant to ITB Clause 39, the Purchaser will promptly notify each unsuccessful Bidder and will discharge its bid security, pursuant to ITB Clause 18.

36.3 The notification of award shall constitute the conclusion of contract.

37.Publication of Bid result

The name and address of Successful bidder(s) will be declared and published appropriately.

38. Signing of Contract

38.1 Promptly after the Purchaser notifies the successful Bidder that its bid has been accepted, the Purchaser will send the Bidder the Contract Form provided in the Bidding Documents, incorporating all agreements between the parties.

38.2 Within twenty-one (21) days of receipt of the Contract Form, the successful Bidder shall sign the Contract Form and return it to the Purchaser.

39. Performance Security

39.1 With in twenty one days (21) days of the receipt of notification of award from the purchaser, the successful bidder shall furnish the performance security in accordance with the conditions of contract, using the performance security form provided in the bidding documents, or any another form acceptable to the purchaser.

39.2 Failure of the successful Bidder to comply with the requirement of ITB Clause 38 or ITB Sub-Clause 39.1 shall constitute sufficient grounds for the annulment of the award and forfeiture of the bid security, in which event the Purchaser may make the award to the next-lowest evaluated bid submitted by a qualified Bidder or call for new bids.

40. Clarification on Duties & Taxes

40.1 **EXCISE DUTY**

40.1.1 The price quoted should be-EXW and the rate of excise duty and quantum of Excise Duty should be shown separately & distinctly. In the absence of any such stipulation it will be presumed that the price includes Excise Duty and no separate claim for the same will be entertained. If in-case of stipulation in the bid, like 'Excise duty extra' or 'As applicable', the quoted prices will be loaded with the maximum quantum of excise duty which is normally applicable on the item in question for the purpose of comparing the prices with other bidders.

40.1.2 If a bidder is exempted from payment of excise duty up to any monetary limit of supplies, he should clearly state that 'no excise duty will be charged by the firm up to the limit of exemption'. In such case, their quoted prices will be loaded with the maximum quantum of excise duty which is normally applicable on the item in question for the purpose of comparing their prices with other bidders unless in such cases it is clearly stated by the bidder that excise duty will not be charged by him even if the same becomes applicable later on. If any concession is available in regard to the rate/quantum of Central Excise Duty, it should be brought out clearly. Stipulations like 'Excise duty presently not applicable but the same will be charged if it becomes leviable later on', will not be accepted (unless in such cases it is clearly stated by the bidder that excise duty will not be charged by him even if the same becomes applicable later on). In respect of the bidders who fail to comply with this requirement, their quoted prices will be loaded with the maximum quantum of excise duty which is normally applicable on the item in question for the purpose of comparing their prices with other bidders.

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40.1.3 Any change in Excise Duty upward/downward as a result of any statutory variation in excise, on the finished goods, taking place during currency of contract shall be allowed to the extent of actual quantum of excise duty paid by the supplier. Similarly in case of

downward revision in excise duty, the actual quantum of reduction in excise duty shall be reimbursed to the Purchaser by the Supplier. All such adjustments shall include all relief's, exemptions, rebates, concessions etc if any obtained by the supplier.

40.1.4 Bidders should note that in case any refund of excise duty is granted to them by excise Authorities in respect of goods supplied under the contract they will pass on the credit to the purchaser immediately, along with a certificate from their Director /Manager/ Proprietor/Accountant that the credit so passed-on relates to the excise originally paid for the goods supplied under the contract. In case of failure to do so within 10 days of the issue of the excise duty refund orders to them by the Excise Authorities, the purchaser would be empowered to deduct a sum equivalent to the amount refunded by the Excise authorities without any further reference to them from any of their outstanding bills against the contract or any other pending Government contract and that no disputes on this account would be raised by them.

40.1.5 The purchaser shall not be liable for any claim on account of fresh imposition and/ or increase of Excise Duty on raw materials and/or components used directly in the manufacture of the contracted stores taking place during the pendency of the contract.

40.1.6 The bidder should indicate in their offer whether they are registered with Excise authorities for availing CENVAT credit or not. If they are availing CENVAT CREDIT, they should take into account the entire credit on inputs available under CENVAT CREDIT Scheme while quoting the price and furnish a declaration to this effect.

40.2 **SALES TAX /VAT**

40.2.1 The price quoted should be exclusive, of Sales Tax/VAT. The element of CST/VAT leviable should be specifically stated and shown separately & distinctly as a percentage along with the price-quoted. Where this is not done, no claim for sales tax will be admitted at any later stage on any ground. Further in the absence of any such stipulation regarding sales tax in the bid, it will be presumed that the prices quoted by the bidder are inclusive of sales tax and no liability for payment of sales tax will be devolved up on the purchaser. If in-case of stipulation like ‘Sales Tax/VAT extra’ or ‘As applicable’, the quoted prices will be loaded with the maximum quantum of Sales Tax/VAT which is normally applicable on the item in question for the purpose of comparing the prices with other bidders.

Any change in Sales Tax upward/downward as a result of any statutory variation in element of CST/VAT leviable, on the finished goods, taking place during currency of contract shall be allowed to the extent of actual quantum of CST/VAT paid by the supplier. Similarly in case of downward revision in CST/VAT, the actual quantum of

reduction in CST/VAT shall be reimbursed to the Purchaser by the Supplier. All such adjustments shall include all relief's, exemptions, rebates, concessions etc if any obtained by the supplier.

40.2.2 For the bidder quoting sales tax extra, sales tax will be paid to the bidder at the rate at which it is liable to be assessed or has actually been assessed provided the transaction of sales is legally liable to sales tax and the same is payable as per terms of the contract.

40.2.3 The purchaser shall not be liable for any claim on account of fresh imposition and/or increase of sales tax/VAT on raw materials and or components used directly in the manufacture of the contracted goods taking place during the pendency of the contract.

40.2.4 The bidder shall unconditionally pass on applicable input tax credit or set off of tax paid on raw materials under the relevant VAT/Sales Tax Act availed on inputs used in manufacture of the finished product. The bidder shall furnish a declaration to this effect.

40.3 **OCTROI DUTY AND LOCAL TAXES**

40.3.1 Goods to be supplied to Govt. Departments against Government Contracts are exempted from levy of Town duty, Octroi Duty, Terminal Tax and other levies of local bodies. The local Town/Municipal Body regulations at times, however, provide for such Exemption only on Production of such exemption certificate from an authorised officer. Supplier should ensure that, goods ordered against contracts placed by this department are exempted from levy of Town Duty, Octroi Duty, Terminal Tax or other Local Taxes and Duties. Wherever required, supplier should obtain the exemption certificate from the concerned office to avoid local taxes or duties.

40.3.2 In case where the Municipality or other local body insists upon payment of these duties or taxes, the same should be paid by the supplier to avoid delay in supplies and possible demurrage charges. The receipt obtained for such payment should be forwarded to the officer concerned without delay together with a copy of the relevant act or by laws/notifications of the Municipality or the Local body concerned to enable him to take up the question of refund with the concerned bodies, if admissible under the said acts or rules.

40.4 **CUSTOMS DUTY**

In respect of imported stores offered from abroad, the bidder shall specify the rate as well as the total amount of customs duty payable and also the customs duty payable with CDEC, if applicable, on the quoted goods in the price schedule. The bidder shall also indicate the corresponding Indian Customs Tariff Number applicable for the goods in question.

Any variation to the custom duty during the currency of the contract will be reimbursed to the bidder/refunded by the bidder. However no upward variation will be reimbursed to the bidder after the expiry of the original delivery period.

41. Purchase preference

41. The Purchaser reserves the right to give purchase preference to the Micro and Small Scale Enterprises as per the policies of Govt. of India in vogue, for which bidder should produce valid copy of his registration as Micro or Small Scale Enterprise.

42. Registration of Imported goods

42. Bidder intending to supply the imported goods must ensure that the goods and the manufacturing facilities of the manufacturer are registered with the relevant authorities in India, as per relevant laws of the country on the date of bid opening. Bidders are advised to visit website www.cdsco.nic.in for necessary information on the subject. Bidders are required to furnish a copy of the aforesaid registration along with their bid.

43. Integrity Pact

43.(i) The Bidder/Supplier is required to enter into an Integrity Pact with the Purchaser, in the Format at Sample Forms Section V.The Integrity Pact enclosed as Form No.12 will be signed by RITES for and on behalf of Purchaser as its Agent/Power of Attorney Holder at the time of execution of Agreement with the successful Bidder. While submitting the Bid, the Integrity Pact shall be signed by the duly authorized signatory of the Bidder/Lead Member of JV. In case of failure to submit the Integrity Pact duly signed and witnessed, along with the Bid, the Bid is likely to be rejected.

43.(ii) In case of any contradiction between the Terms and Conditions of the Bid Document and the Integrity Pact, the former will prevail.

Name and Address of the Independent External Monitor (In case value of contract is Rs.10 crores or more): Shri B. S. Minhas, A-29, Bhairon Marg, Hanuman Nagar, Jaipur-302021

Name, Designation and Address of RITES' Liaison Officer (in case value of contract is less than Rs.10 crores): Shri Y. K. Sharma, GM/CP

SECTION II.

GENERAL CONDITIONS OF CONTRACT

TABLE OF CLAUSES

General Conditions of Contract

1. Definitions

1.1 In this Contract, the following terms shall be interpreted as indicated:

(a) "The Contract" means the agreement entered into between the Purchaser and the Supplier, as recorded in the Contract Form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.

(b) "The Contract Price" means the price payable to the Supplier under the Contract for the full and proper performance of its contractual obligations.

(c) "Day" means calendar day.

(d) "Effective Date" means the date on which this Contract becomes effective i.e. date of notification of Award.

(e) "GCC" means the General Conditions of Contract contained in this section.

(f) "The Goods" means all of the pharmaceuticals and others including nutritional supplement and oral and injectable forms of contraception, vaccines, and condoms that the Supplier is required to supply to the Purchaser under the Contract.

(g) "The Purchaser" means Ministry of Health & Family Welfare, Govt. of India through RITES Ltd, New Delhi. Purchaser will exercise all rights and obligation under this contract through the Procurement Agent pursuant to the Agreement between the Ministry of Health and Family Welfare (MOHFW), Government of India and RITES Ltd.

(h) "The Purchaser's Country" is India.

(i) "Registration Certificate" means the certificate of registration or other documents in lieu thereof establishing that the Goods supplied under the Contract are registered for use in India in accordance with the Applicable Law.

(j) "The Services" means those services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as provision of technical assistance, training, and other such obligations of the Supplier

covered under the Contract.

(k) "The Site," where applicable, means the place or places named in the Schedule of requirement.

(l) "The Supplier" means the individual or firm supplying the Goods and Services under this Contract.

m) End user means the organization(s) where the goods will be used.The end user is the consignee stated in the Schedule of Requirements

2. Imports

For Import origin goods quoted, the supplier or the Indian agent shall have to arrange at his own cost, all import/custom clearance handling facilities. The purchaser shall not be liable to any claim on account of fresh imposition and/or increase of Excise Duty, Custom Duty, Sales Tax on raw materials and /or components used directly in the manufacture of the contracted goods taking place during the pendency of the contract.

3. Application

3.1 These General Conditions shall apply to the extent that they are not superseded by provisions of other parts of the Contract.

4. Country of Origin

4.1 Any Goods and Services supplied under the Contract shall have their origin in India or eligible countries (in case of imported goods offered) with which India has not banned trade relations.

For purposes of this Clause, "origin" means the place where the Goods were mined, grown, or produced, or from which the Services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.

5. Standards

5.1 The Goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications and, when no applicable standard is mentioned, to the authoritative standards appropriate to the Goods' country of origin. Such standards shall be the latest issued by the concerned institution.

5.2 If required under the applicable law, Goods supplied under the contract shall be registered for use in the purchasers country.

6. Use of Contract Documents and Information; Inspection and Audit by the Purchaser	6.1	The Supplier shall not, without the Purchaser's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the Purchaser in connection therewith, to any person other than a person employed by the Supplier in the performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.
	6.2	The Supplier shall not, without the Purchaser's prior written consent, make use of any document or information enumerated in GCC Sub-Clause 6.1 except for purposes of performing the Contract.
	6.3	Any document, other than the Contract itself, enumerated in GCC Sub-Clause 6.1 shall remain the property of the Purchaser and shall be returned (all copies) to the Purchaser on completion of the Supplier's performance under the Contract if so required by the Purchaser.
	6.4	The Supplier shall permit the Purchaser to inspect the Supplier's accounts and records relating to the performance of the Contract and to have them audited by auditors appointed by the Purchaser, if so required by the Purchaser.
7. Patent Rights	7.1	The Supplier shall indemnify the Purchaser against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the Goods or any part thereof in India.
8. Performance Security	8.1	Within twenty-one (21) days of receipt of the notification of Contract award, the successful Bidder shall furnish to the Purchaser the performance security in the amount equal to 10 % of the total contract price. a) In the event of any amendment issued to the Contract, the Supplier shall, within twenty-one (21) days of issue of the amendment, furnish the corresponding amendment to the Performance Security (as necessary) rendering the same valid in all respects in terms of the Contract, as amended. b) The performance security shall be valid till **90 days** after the date of completion of all contractual obligations including warranty.
	8.2	The proceeds of the performance security shall be payable to the Purchaser as compensation for any loss resulting from the

Supplier's failure to complete its obligations under the Contract. For the purpose of this clause each schedule constitutes separate contract

8.3 The performance security shall be denominated in Indian Rupees or in the currency of the contract and shall be in one of the following forms:

(a) The performance security shall be in the form of a (bank) guarantee issued by a nationalized/scheduled bank in India and the named beneficiary shall be "RITES Ltd" (acting as procurement agent on behalf of Ministry of Health & Family Welfare Government of India). The format of the (bank) guarantee shall be in accordance with the form given in Section V. In the case of Bank Guarantee furnished from banks outside India, it should be authenticated and countersigned by any Nationalised or Scheduled bank in India to make it enforceable and acceptable to the purchaser.
Letter of credit is not acceptable.

(b) an unconditional bank guarantee issued by a nationalized/scheduled bank located in India and acceptable to the Purchaser, in the format provided in the Bidding Documents; or

c) a crossed demand draft or a pay-order drawn in favour of the Purchaser.

8.4 The performance security will be discharged by the Purchaser and returned to the Supplier not later than thirty (30) days following the date of completion of the Supplier's performance obligations under the Contract, including any warranty obligations.

9. Inspections and Tests

9.1 The Purchaser or its representative shall have the right to inspect and/or to test the Goods to confirm their conformity to the Contract specifications. All goods consumed during testing will be on supplier's account.

The Technical Specifications (Section IV) shall specify what inspections and tests the Purchaser requires and where they are to be conducted.

For the Goods supplied from within India, the goods shall not be dispatched unless they are inspected and cleared for dispatch by Purchaser's representative.

For Goods offered from outside India, the Purchaser reserves the right to inspect prior to shipment at the manufacturer's premises. For such goods, the supplier shall submit with each consignment, the Batch Certificate of Pharmaceutical Product' in conformity with WHO Certification Scheme. The Batch Certificate shall be issued by the regulatory authority of the exporting country. A certificate issued by the manufacturer will not be acceptable.

On arrival at the port of entry, for goods dispatched from outside India each consignment shall further be tested by the Drug Controller of India or his representative. For this purpose, the Purchaser shall notify the Drug Controller General of India (DCGI) (or his representative) about the expected arrival of the consignment at the port of entry. On the arrival of the goods, the representative of the Drug Controller General of India (DCGI) will examine/test the consignment and after satisfying himself that the goods conform to the technical specifications, he will clear the consignment. Only such goods are permitted to enter the country which is found to fully conform to the technical specifications. The cost of DCGI inspection/testing will not be charged to the supplier but all goods consumed during testing will be on suppliers account.

The supplier will make arrangements for storage of goods in the port of entry at their cost and will be responsible for costs arising from the storage, warehousing and demurrage. The costs of the pre-shipment inspection of goods along with the cost for taking samples shall be borne by the Purchaser.

The supplier shall at the earliest furnish details of number of batches and visits for inspection and testing to enable the pre-dispatch inspection and testing when undertaken.However if the goods are offered for inspection in much variance then supplier will have to bear the additional inspection/testing charges.

The cost of subsequent inspections and related costs, due to rejection of Goods at the first inspection shall be borne by the Supplier. Inspection will be done by a Purchaser's agent to ascertain whether the Goods are in conformity with the technical specifications of the contract or not.

The Supplier shall put up the goods for such inspection to the Purchaser's inspector 15-25 days (depending on the time required for pre-dispatch inspection & testing) ahead of the

contractual delivery period, so that deliveries to the consignees are completed as per the contractual delivery period.

Further,

(a) Pre-dispatch inspection of the supplies shall be conducted by purchaser or its authorised representative retained by the purchaser for these purposes. The related cost of the pre-shipment inspection including sampling for the first inspection of goods shall be borne by the purchaser. The Purchaser shall notify the Supplier in writing, in a timely manner, of the identity of any representatives retained for these purposes.

(b) Batch wise inspection of goods shall be carried out by Purchaser's representative. The Supplier shall at the earliest furnish details of number of batches and visits for inspection and testing to enable the pre-dispatch inspection and testing when undertaken.

(c) Said inspection and testing is for the Purchaser's account. In the event that inspection and testing is required prior to dispatch, the Goods shall not be shipped unless a satisfactory inspection and quality control report has been issued in respect of those Goods.

(d) The Supplier may have an independent quality test conducted on a batch ready for shipment. The cost of such tests will be borne by the Supplier.

(e) Upon receipt of the Goods at place of final destination, the end user/consignee shall have the right to inspect the Goods or part of the Goods to ensure that they conform to the condition of the Contract and advise the Purchaser that the Goods were received in apparent good order. The end user/consignee will issue an Acceptance Certificate to the Supplier in respect of such Goods (or part of Goods). The Acceptance Certificate shall be issued within twenty one (21) days of receipt of the Goods or part of Goods at place of final destination.

Regardless of any pre-shipment inspection (and the result thereof) undertaken by the Purchaser, the Purchaser/Consignee may inspect and/ or test the Goods at final destination.

9.2 Where the Supplier contests the validity of the rejection by the Purchaser or his representative, of any inspection as required by 9.1 above, conducted before shipment or at ultimate

destination, whether based on product or packing grounds, a sample drawn jointly by the Supplier and Purchaser or his or her representative and authenticated by both, will be forwarded for umpire analysis within four weeks of the time the Supplier contests to an independent agency mutually agreed by the Purchaser and Supplier. The umpire's finding, which will be promptly obtained, will be final and binding on both parties. The cost of umpire analysis will be borne by the losing party.

10. Packing

10.1 The Supplier shall provide such packing of the Goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt, and precipitation during transit and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the Goods' final destination and the absence of heavy handling facilities at all points in transit.

10.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements strictly as per Technical Specifications, and in any subsequent instructions ordered by the Purchaser before clearing for dispatch. The bar coding requirement shall also be properly understood and marked on the package as per the provision of the specification.

11. Delivery and Documents

The details of shipping and/or other documents, as applicable under I or II below, to be furnished by the Supplier are:

I For Goods supplied from abroad:

(A) Documents to be submitted to purchaser: -

Upon shipment, within 24 hours the Supplier shall notify the Purchaser in writing the full details of the shipment including Contract number, description of the Goods, quantity, date and port of shipment, mode of shipment, estimated dates of arrival at the port of entry and the place of destination. In the event of Goods sent by airfreight, the Supplier shall notify the Purchaser a minimum of Seventy-Two (72 hours) ahead of dispatch, the name of the carrier, the flight number, the expected date and time of arrival, the Master airway-bill and the House airway- bill numbers. The Supplier shall first fax the above details and then send to the Purchaser, by courier

the following:

(i) One original and three (3) copies of the suppliers commercial invoice, indicating the RITES Ltd as the Purchaser on behalf of Ministry of Health & Family Welfare, Govt. of India, the Contract number, credit number, Goods description, quantity, unit price, and total amount. Invoices must be signed in original and stamped, or sealed with the company stamp/seal.

(ii) One Original and One Copy of negotiable, clean, on-board through bill of lading marked "freight prepaid" and indicating the RITES Ltd as the Purchaser on behalf of Ministry of Health & Family Welfare, Govt. of India, and notify Consignees as stated in the Contract.

(iii) Packing list identifying contents of each package.

(iv) One original of the manufacturer's or Supplier's Warranty Certificate covering all items supplied.

(v) One original of supplier's Certificate of country of origin covering all items supplied.

(vi) One copy of the Internal Test Analysis Report of the Manufacturer for the items offered.

(vii) Original copy of the certificate of Inspection / DCC furnished to Supplier by the nominated agency (where inspection is required).

(viii) One original and six copies of the certificate of weight issued by the port authority/licensed authority.

(ix) One original and three (3) copies Acknowledgement of receipt of Goods by the Consignees, i.e. Consignment Receipt Certificate (CRC) and FAC as per the format after delivery.

(x) Original copy of bill of entry for import clearance for each invoice.

(xi) Any other/additional procurement-specific document(s)s required for delivery/payment purposes, showing delivery through to final destination as per schedule of requirement.

(B) Documents to be submitted to consignee:-

The Supplier shall intimate the Consignee in advance at least 7 days before the dispatch of Goods the expected date of arrival of Goods along with quantity of Goods. Along with each consignment the Supplier shall provide the Consignee one set of the documents mentioned below:

(i) Supplier's Delivery note, indicating Good's description, quantity, batch number, date of expiry etc. Delivery note must be signed in original and stamped or sealed with the company stamp/seal.

(ii) Packing list identifying contents of each package.

(iii) Manufacturers or Supplier's Warranty certificate covering all items supplied.

(iv) Clearance of the Goods by the Drug Controller of India at port of entry in terms of the Clause 9.1.

(v) Copy of batch certificate of Pharmaceutical product

(vi) Inspection Certificate/Dispatch Clearance Certificate in case of Pre Dispatch Inspection.

(viii) Country of Origin certificate.

II. For Goods from within the Purchaser's country:

(A) Documents to be submitted to Purchaser:-

Upon the delivery of the Goods, the Supplier shall notify the Purchaser in writing and deliver to the Purchaser documents comprising of the following:

(i) One original and three (3) copies of commercial invoice, indicating the RITES Ltd .as the Purchaser on behalf of Ministry of Health & Family Welfare, Govt. of India, the Contract number, Credit number; Goods' description, quantity, unit price, and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/seal.

(ii) Proof of Dispatch (POD), viz., Railway consignment note, road consignment note, truck or airway bill, or multimodal transport document showing Purchaser as RITES Ltd. on behalf of Ministry of Health & Family Welfare, Govt. of India and delivery through to final destination (DDP Consignee End) as stated in the Contract.

(iii) One original and three (3) copies Acknowledgement of receipt of Goods by the Consignees, i.e. Consignment Receipt Certificate (CRC) and FAC as per the format.

(iv) Packing list identifying contents of each package.

(v) One original manufacturer's or Supplier's Warranty certificate covering all items supplied.

(vi) One original of the Supplier's Certificate of Origin covering all items supplied.

(vii) One original and 3 copies of Certificate of Inspection furnished to Supplier by the nominated inspection agency (where inspection is required).

(viii) Internal Test Analysis Report and batch certificate of pharmaceutical products and/or medical devices of the Manufacturer.

(ix) Copy of notification of the local tax authority in support of rate of tax indicated in invoice.

(x) Any other/additional procurement-specific document(s) required for delivery/payment purposes.

(B) Documents to be submitted to Consignee: -

(i) The Supplier should intimate the Consignee in advance at least 7 days before the dispatch of Goods the expected date of arrival of Goods along with quantity of Goods. Along with each consignment the Supplier should provide the Consignee one set of the documents mentioned below:

(ii) Supplier's Delivery note, indicating Good's description, quantity, batch number, date of expiry etc. Delivery note must be signed in original and stamped or sealed with the company stamp/seal.

(iii) Packing list identifying contents of each package

(iv) Manufacturers or Supplier's Warranty certificate covering all items supplied.

(v) Country of Origin certificate

For both I and II above:

All documents submitted to the purchaser and consignee shall be

countersigned by authorised signatory of the supplier.

Supplier shall submit an affidavit as per sample form 10 (section V), alongwith bills for claiming payment.

In the event that the documents presented by the Supplier are in accordance with the Contract, then payment will be made against issue of the Final acceptance Certificate.

It will be the responsibility of the Supplier to obtain from the Purchaser (RITES), Customs Duty Exemption Certificate or Excise Exemption Certificate, as may be applicable, and the Purchaser shall not be responsible for any expenditure arising out of the Supplier's inability to obtain the necessary certificate(s) in time.

The bill for payment should also be accompanied by the following certificate to be furnished by the Suppliers who are registered with excise authorities for availing CENVAT credit:

"We certify that no additional duty set offs on the stores supplied by us, have accrued under the CENVAT credit scheme in force on the date of supply, after we submitted quotations and submitted the present bill"

12. Insurance Deleted

13. Transportation 13.1 Where the Supplier is required under the Contact to transport the Goods to a specified place of destination within India, defined as the Site, transport to such place of destination in India, including insurance and storage, as shall be specified in the Contract, shall be arranged by the Supplier, and related costs shall be included in the Contract Price.

14. Incidental Services 14.1 The Supplier shall provide such incidental services:-

(a) The Supplier shall provide all necessary licenses and permissions for use of the Goods in India that may be required for the Goods. The cost shall be deemed to be included in the Contract Price.

(b) The Supplier shall provide such other services as are stated in the Technical Specifications.

15. Warranty 15.1 All goods must be of fresh manufacture and must bear the dates of manufacture and expiry.

The Supplier further warrants that all Goods supplied under the Contract will have remaining a minimum of five-sixths (5/6) of the specified shelf life upon delivery at site or named place of destination in India for goods with a shelf life of more than two years and three-fourths (3/4) for goods with a shelf life of two years or less, have "overages" within the ranges set forth in the Technical Specifications, where applicable; are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect will fully comply in all respects with the Technical Specifications and with the conditions laid down in the Contract.

15.2 The Purchaser shall have the right to make claims under the above warranty up to the **full period of shelf life of goods plus three (3) Months.** Upon receipt of a written notice from the Purchaser, the Supplier shall, with all reasonable speed, replace the defective Goods without cost to the Purchaser. The Supplier will be entitled to remove, at his own risk and cost, the defective Goods once the replacement Goods have been delivered.

15.3 In the event of a dispute by the Supplier, a counter analysis will be carried out on the manufacturer's retained samples by an independent neutral laboratory agreed by both the Purchaser and the Supplier. If the counter analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective goods. In the event of the independent analysis confirming the quality of the product, the Purchaser will meet all costs for such analysis.

15.4 If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 15.2 above, the Supplier fails to replace the defective Goods within the period of **30 days**, the Purchaser may proceed to take such remedial action as may be necessary, including removal and disposal, at the Supplier's risk and expense and without prejudice to any other rights that the Purchaser may have against the Supplier under the Contract. The Purchaser will also be entitled to claim for storage in respect of the defective Goods for the period following notification and shall have the right to deduct the sum from payments due to the Supplier under this Contract or any other contract.

The date of receipt of replacement supplies at consignee will be treated as the date of delivery.

15.5 Recalls

In the event any of the Goods are recalled, the Supplier shall notify the Purchaser within fourteen (14) days, providing full details of the reason for the recall and promptly replace, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfil its recall obligation promptly, the Purchaser will, at the Supplier's expense, carry out the recall.

16. Payment

16.1 The method and conditions of payment to be made to the Supplier (Payments will not be made to any other party) under this Contract, as applicable under (A) or (B) below, shall be as follows:

(A) Payment for Goods supplied from abroad:

Payment of foreign currency portion shall be made in the currency of the Contract Price in the following manner:

(i) On Delivery to Consignee: Ninety (90) percent of the Contract Price of the Goods delivered to the Consignee shall be paid on submission of documents specified in GCC Clause 11 above along with Consignee Receipt Certificate (Form 8 of Section V), by Electronic clearing system to the Supplier's nominated bank account through a corresponding bank in India.

(ii) On Acceptance: Ten (10) percent of the Contract Price of Goods received shall be paid on acceptance of the Goods upon submission of an invoice (indicating RITES Ltd. as the Purchaser on behalf of Ministry of Health & Family Welfare, Govt. of India), the Contract number, description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal supported by the Acceptance Certificate (Form-9 of Section V) issued by the Consignee through Electronic clearing system of the bank through a corresponding bank in India.

Payment of local currency portion shall be made in Indian Rupees on presentation of an invoice (indicating the RITES Ltd. as the Purchaser on behalf of Ministry of Health & Family Welfare, Govt. of India) the Contract number, description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal supported by the Acceptance Certificate issued by the Consignee.

(B) Payment for Goods and Services supplied from within the Purchaser's country:

Payment for Goods and Services supplied from within the Purchaser's country shall be made in Indian Rupees, as follows:

(i) On Delivery to Consignee: Ninety (90) percent of the Contract Price of the Goods delivered to the Consignee shall be paid within on submission of documents specified in GCC Clause 11 along with the Consignee Receipt Certificate (Form 8, Section V of the bid document) through ECS.

(ii) On Acceptance: Ten (10) percent of the Contract Price of Goods received shall be paid on acceptance of the Goods upon submission of an invoice (indicating the RITES Ltd., as the Purchaser on behalf of Ministry of Health & Family Welfare, Govt. of India; the Contract number, description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate (Form 9, Section V of the bid document) issued by the Consignee through ECS.

16.2 The Supplier's request (s) for payment shall be made to the Purchaser in writing, accompanied by an invoice describing, as appropriate, the Goods delivered and Services performed, and by documents submitted pursuant to GCC Clause 11 & 16.1, and upon fulfilment of other obligations stipulated in the Contract.

17. Prices

Prices charged by the supplier for Goods delivered and Services performed under the Contract shall not vary from the prices quoted by the Supplier in its bid for the durationof the Contract.

Prices shall be fixed and firm for the duration of the Contract. However sales tax wherever payable shall be paid as appliacable at the time of supply. Statutory variations are permitted during the original delivery schedule and not in the extended delivery schedule.

Bidders are required to comply with following conditions:

a. In case of any ceiling prices fixed by Government of India for the formulations as per the contract within the validity of the contract, the lesser of the two prices viz. the unit prices in the contract and the ceiling prices, will be applicable for the entire quantities in the contract.

b.. If the supplier supplies the same formulations in the contract at lesser unit prices to any other party during the validity of the contract, the unit prices in this contract shall also be reduced to match with those lesser prices. Firm shall give a declaration for this at the time of submission of their bills.

18. Change Orders

18.1 The Purchaser may at any time, by a written order given to the Supplier pursuant to GCC Clause 31, make changes within

the general scope of the Contract in any one or more of the following:

(a) specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Purchaser;

(b) the method of shipment or packing;
(c) the place of delivery; and/or

(d) the Services to be provided by the Supplier.

e) The Purchaser reserves the right to increase or decrease the quantity of goods by 20% at time of award or during the currency of contract. The quantity of goods and services beyond that originally specified in the Schedule of Requirements shall be without any change in unit price or other terms & conditions. Delivery period for additional quantity under tolerance clause shall be on pro-rata basis of original delivery.

18.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or delivery schedule, or both, and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this clause must be asserted within thirty (30) days from the date of the Supplier's receipt of the Purchaser's change order.

19. Contract Amendments

19.1 Subject to GCC Clause 18, no variation in or modification of the terms of the Contract shall be made except by written amendment signed/agreed by the Purchaser and Supplier.

20. Assignment

20.1 The Supplier shall not assign, in whole or in part, its obligations to perform under this Contract, except with the Purchaser's prior written consent.
Assignment and sub-contracting, which is not disclosed in bid, are not permitted.

21. Delays in the Supplier's Performance

21.1 Delivery of the goods shall be made by the supplier in accordance with the time schedule specified in the contract. Any deviation in performance of its delivery obligations shall render the supplier liable to any or all of the following action.

(a) Forfeiture of its Performance Security and / or
(b) Imposition of liquidated damages and/or

(c) Termination of the contract for default.

21.2 If at any time during the performance of the contract, the supplier should encounter conditions impending timely delivery of the goods, the supplier shall promptly notify the purchaser in writing of the facts of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the suppliers notice, the purchaser shall evaluate the, situation and may at its discretion extend the supplier time for performance in which case the extension shall be ratified by the parties by amendment to the contract. The extension of the delivery period will be subject to the following conditions.

a) The Purchaser shall deduct from the supplier under the provision of Clause 22 liquidated damages on the goods, which the supplier has failed to deliver within the delivery period fixed for delivery.

b) That no increase in price on account of any statutory increases in or fresh imposition of customs duty, excise duty or sales tax or on account of any other tax or duty leviable in respect of the goods specified in the contract which takes place after the date of the delivery period stipulated in the contract, shall be admissible on such of the said goods as are delivered after the date of delivery stipulated in the contract.

c) But nevertheless, the purchaser shall be entitled to the benefit of any decrease in price on account of reduction in or remission of Customs duty, Excise Duty, Sales Tax or on *account of* any other tax or duty or on any other grounds which takes place after the expiry of the date of delivery stipulated in the contract.

21.3 Except as provided under GCC Clause 24, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Clause 21.2 without the application of liquidated damages.

22. Liquidated Damages

22.1 Subject to GCC Clause 24, if the Supplier fails to deliver any or all of the Goods or to perform the Services within the period(s) specified in the contract, the Purchaser shall, without prejudice to its other remedies under the Contract, deduct from the supplier's bills, as liquidated damages, a sum equivalent to the 0.5 percent per week or part thereof of the delivered price of the delayed Goods or unperformed Services

for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the 10 percent of the value of delayed Goods. Once the maximum is reached, the Purchaser may consider termination of the contract pursuant to GCC Clause 23. For the purpose of this clause each schedule constitute separate contract.

23. Termination for Default

23.1 The Purchaser, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate the Contract in whole or in part:

(a) if the Supplier fails to deliver any or all of the Goods within the period(s) specified in the contract, or within any extension thereof granted by the Purchaser pursuant to GCC Clause 21; or/and

(b) if the Goods do not meet the Technical Specifications stated in the Contract; or/and

(c) if the supplier fails to provide any registration or other documents in respect of the goods within reasonable time as specified in the contract.

(d) if the Supplier, in the judgment of the Purchaser, has engaged in corrupt or fraudulent practices in competing for or in executing the Contract.

For the purpose of this clause:

"corrupt practice" means the offering, giving, receiving, or soliciting of any thing of value to influence the action of a public official in the procurement process or in Contract execution.

"fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a Contract to the detriment of the Purchaser, and includes collusive practice among Bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the Purchaser of the benefits of free and open competition.

(e) if the Supplier fails to perform any other obligation(s) under the Contract.

23.2 In the event the Purchaser terminates the Contract in whole or in part, pursuant to GCC Clause 23.1, the Purchaser may procure, upon such terms and in such manner as it deems appropriate, Goods or Services similar to those undelivered, and the Supplier shall be liable to the Purchaser for any excess

costs for such similar Goods or Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.

24. Force Majeure

24.1 Notwithstanding the provisions of GCC Clauses 21, 22, and 23, the Supplier shall not be liable for forfeiture of its performance security, imposition of liquidated damages, or termination for default if and to the extent that its delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.

24.2 For purposes of this clause, "Force Majeure" means an event beyond the control of the Supplier and not involving the Supplier's fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the Purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes.

24.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

25. Termination for Insolvency

25.1 The Purchaser may at any time terminate the contract by giving written notice to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the Supplier, provided that such termination will not prejudice or affect any right of action or remedy that has accrued or will accrue thereafter to the Purchaser.

26. Termination for Convenience

26.1 The Purchaser, by written notice sent to the Supplier, may terminate the contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the Purchaser's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.

26.2 The Goods that are complete and ready for shipment within thirty (30) days after the Supplier's receipt of notice of termination shall be accepted by the Purchaser at the Contract terms and prices. For the remaining Goods, the Purchaser may elect:

(a) to have any portion completed and delivered at the contract terms and prices; and/or

(b) to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Services and for materials and parts previously procured by the Supplier.

27. Settlement of Disputes

27.1 If any dispute or difference of any kind whatsoever shall arise between the Purchaser and the Supplier in connection with or arising out of the Contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.

27.2 If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the Purchaser or the Supplier may give notice to the other party of its intention to commence arbitration, as hereinafter provided, as to the matter in dispute, and no arbitration in respect of this matter may be commenced unless such notice is given.

27.2.1 Any dispute or difference in respect of which a notice of intention to commence arbitration has been given in accordance with this Clause shall be finally settled by arbitration. Arbitration may be commenced prior to or after delivery of the Goods under the Contract.

27.2.2 Arbitration proceedings shall be conducted in accordance with the rules of procedure which are as follows:-.

A: For Domestic Supplier

(a) In case of Dispute or difference arising between the Purchaser and a supplier relating to any matter arising out of or connected with this agreement, such disputes or difference shall be settled in accordance with the Arbitration and Conciliation Act, 1996 of India. The arbitral tribunal shall consist of 3 Arbitrators one each to be appointed by the Purchaser and the Supplier. The third Arbitrator shall be chosen by the two Arbitrators so appointed by the Parties and shall act as Presiding arbitrator. In case of failure of the two arbitrators appointed by the parties to reach upon a consensus within a period of 30 days from the appointment of the arbitrator appointed subsequently, the Presiding Arbitrator shall be appointed by the Medical Council of India.

(b) Where the value of the contract is Rs.10 million and below, the disputes or differences arising shall be referred to the Sole Arbitrator. The Sole Arbitrator should be appointed by agreement between the parties; failing such agreement, by the Medical Council of India.

(c) If one of the parties fails to appoint its arbitrator in pursuance of sub-clause (a) above, within 30 days after receipt of the notice of the appointment of its arbitrator by the other party, then the Medical Council of India shall appoint the arbitrator. A certified copy of the order of the Medical Council of India making such an appointment shall be furnished to each of the parties.

(d) The venue of Arbitration shall be the place from where the contract is issued and the language of the arbitration proceedings and that of all councils and communications between the parties shall be English.

(e) The decision of the majority of arbitrators shall be final and binding upon parties. In case there is no majority decision, the decision of the Presiding arbitrator shall be final. The cost and expenses of Arbitration proceedings will be paid as determined by the arbitral tribunal. However, the expenses incurred by each party in connection with the preparation, presentation, etc. of its proceedings as also the fees and expenses paid to the arbitrator appointed by such party or on its behalf shall be borne by each party itself.

(f) The Arbitration and Conciliation Act of 1996 the rules herewith and any statutory modification or re-enactment thereof shall apply to arbitration proceedings.

B. For Foreign Supplier:

a) In case of Dispute with a foreign supplier, the dispute shall be settled in accordance with provision of UNCITRAL (United Nations Commission on International Trade Law) Arbitration Rules. The Arbitral Tribunal shall consist of 3 Arbitrators one each to be appointed by the Purchaser and the Supplier. The third Arbitrator shall be chosen by the two Arbitrators so appointed by the Parties and shall act as presiding arbitrator. In case of failure of the two arbitrators appointed by the parties to reach upon a consensus within a period of 30 days from the appointment of the arbitrator appointed subsequently, the Presiding Arbitrator shall be appointed by the Medical Council of India.

(b) If one of the parties fails to appoint its arbitrator in pursuance of sub-clause (a) above, within 30 days after receipt of the notice of the appointment of its arbitrator by the other party, then the Medical Council of India, shall appoint the arbitrator. A certified copy of the order of the Medical Council of India making such an appointment shall be furnished to each of the parties.

(c) The venue of Arbitration shall be the place from where the contract is issued and the language of the Arbitration Proceedings and that of all councils and communications between the parties shall be English.

(d) The decision of the majority of arbitrators shall be final and binding upon parties. In case there is no majority decision, the decision of the Presiding arbitrator shall be final. The cost and expenses of Arbitration Proceedings will be paid as determined by the arbitral tribunal. However, the expenses incurred by each party in connection with the preparation, presentation, etc. of its proceedings as also the fees and expenses paid to the Counsel appointed by such party or on its behalf shall be borne by each party itself.

27.3 Notwithstanding any reference to arbitration herein,

(a) the parties shall continue to perform their respective obligations under the Contract unless they otherwise agree; and
(b) the Purchaser shall pay the Supplier any monies due to the Supplier.

28. Limitation of Liability

28.1 Except in cases of criminal negligence or wilful misconduct, and in the case of infringement pursuant to Clause 7,

(a) the Supplier shall not be liable to the Purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay liquidated damages to the Purchaser and
(b) the aggregate liability of the Supplier to the Purchaser, whether under the Contract, in tort or otherwise, shall not exceed the total price of contract, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.

29. Governing

29.1 The Contract shall be written in English language. All

Language correspondence and other documents pertaining to the Contract that are exchanged by the parties shall be written in the same language.

30. Applicable Law 30.1 The Contract shall be interpreted in accordance with the laws of Union of India.

31. Notices 31.1 Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing or by cable, e-mail, or facsimile and confirmed in writing to the other party's address are as follows: -

The Purchaser's addresses for notice purposes is:

Group General Manager-MSM
RITES Ltd., RITES Office Complex-2,
Annexe Building, MSM Division 4th floor,
Plot No-144, Sec-44,
Gurgaon-122003(Haryana),
India

The Supplier's address for notice purposes is as mentioned in the NOA/contract.

31.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

32. Taxes and Duties 32.1 The Supplier shall be entirely responsible for all taxes, duties, octroi, road permits, license fees, etc., incurred until delivery of the Goods to the Purchaser.

33. Jurisdiction All disputes arising out of the contract shall (subject to clause 27) be subject to the jurisdiction of the appropriate court at New Delhi, India, only.

SECTION III.

SCHEDULE OF REQUIREMENTS

SECTION III
SCHEDULE OF REQUIREMENTS

Schs No	Item	Unit	Qty	Bid Security in INR	Bid Security in US$
I	Amphotericin Injection	Nos	15,000	41,000.00	700.00
II	Amphotericin Injection	Nos	25,000	68,000.00	1,100.00
	Sub-total		**40,000**	**1,09,000.00**	**1,800.00**
III	Paramomycin injection	Nos	27,900	96,000.00	1,500.00
IV	Paramomycin injection	Nos	30,000	1,03,000.00	1,700.00
	Sub-total		**57,900**	**1,99,000.00**	**3,200.00**
V	Artesunate Injection Kit	Nos	39,000	53,000.00	900.00
VI	Artesunate Injection Kit	Nos	35,000	48,000.00	800.00
VII	Artesunate Injection Kit	Nos	49,000	67,000.00	1,100.00
VIII	Artesunate Injection kit	Nos	50,000	67,000.00	1,100.00
IX	Artesunate Injection kit	Nos	37,000	50,000.00	800.00
	Sub-total		**2,10,000**	**2,85,000.00**	**4,700.00**

1st lot - 70 % of the total quantity within 90 days after the issue of NOA

IInd lot - 30% of the quantity after 270 days and before 300 days from the issue of NOA.

Terms of Delivery for each Consignee:
Final Destination at the consignee end as per Schedule of Requirements..(DDP consignee End as per INCOTERMS)

Consignee-wise Quantity distribution

Schs No	Consignees	Consignee-wise Qty
I	Jharkhand	6,000
	West Bengal	2,000
	GMSD kolkata	7,000
II	Bihar	25,000
		40,000
III	Jharkhand	9,000
	West Bengal	4,000
	GMSD kolkata	14,900
IV	Bihar	30,000
		57,900
V	Andhra pradesh	7,000
	GMSD Hyderabd	15,000
	GMSD Chennai	15,000
	Karnataka	2,000
VI	Maharashtra	8,000
	GMSD Mumbai	10,000
	Gujarat	6,000
	Rajasthan	1,000
	GMSD Karnal	10,000
VII	Madhya Pradesh	15,000
	Chattisgarh	34,000
VIII	Orissa	50,000
IX	Jharkhand	22,000
	West Bengal	5,000
	GMSD Kolkata	10,000
		2,10,000

Consignee Address

Consignee	***Address***	***Telephone***	***Fax***	***E-mail***
Hyderabad, Andhra Pradesh	Addl. Director (Mal. & Fil.), DM&HS Campus, Sultan Bazar, Hyderabad - 500096	040-24618078 04024650334	040-24618078 040-24656852	statemalaria@yahoo.com
Raipur, Chhattisgarh	State Programme Officer, Directorate of Health Services, D.K. Bhawan Campus, Raipur, Chhattisgarh	0771-2234760 0771-2221624	0771-2234760 0771-2221621	omkataria@yahoo.com
Bhopal, Madhya Pradesh	Joint Director (Malaria) Dte. Of Health Services, Satpura Bhawan, 6th Floor, Bhopal, Madhya Pradesh	0755-2553250 0755-4299173	0755-4285268 0755-2576197	smcs-bpl@rediffmail.com
Kolkata, West Bengal	Dy. Director of Health Services (Malaria), West Bengal, Swasth Bhawan, GN – 29, Sector – 5, Salt Lake City, Kolkata – 700091	033 23576069 033-23330269	033-23576788	pd_spsrc@ebhealth.gov.in tots_ spsrc@wbhealth.gov.in
GMSD, Guwahati	ADG (MS), Govt. Medical Stores Depot, A.K. Azad Road, Gopinath Nagar, Guwahati-781016, Assam	0361-2471214	0361-2471214	gh75108@bsnl.in
GMSD, Karnal	ADG (MS), Govt. Medical Stores Depot Post Box No.-8, Karnal – 132001 Haryana	0184-2272437 0184-2252328 0184-2272175 0184-2250233	0184-2252328	medicalstore@dataone.in
GMSD, Kolkata	ADG (MS), Govt. Medical Stores Depot, 9, Clyde Row Hastings, Kolkata-700022, West Bengal	033-22233593 033-22230409 033-22230452 033-22233596 033-22236125	033-22230838	gmsdkol@yahoo.com
GMSD, Mumbai	ADG (MS), Govt. Medical Stores Depot, Post Box No.-4514, Mumbai Central, Mumbai-400008, Maharashtra	022-23082091 022-23082092 022-23078364	022-23074617	gmsdmumbai@yahoo.com
Jharkhand	State Programme Officer, NVBDCP RCH Directorate Namkum, Tata Road Ranchi-835 301, Jharkhand	0651-2260622 0651-2260625 (Mr Vinod) 09431102461	0651-2261199	smo_smcs@yahoo.com smo.smcs@gmail.com pradeep baskey @ yahoo.com
Orissa	Joint Director of Health Services (Mal) Head of Department Building Bhubaneswar-751001, Orissa	0674-2390649 0674-2536038 0674-2394616 09439994863	0674-2391589 0674-2390271	nvbdcporissa@gmail.com
Karnataka	Joint Director (Mal. & Fil.) I/C, Directorate of Health & FW Services, Ananda Rao Circle, Karnataka,BANGALURU-560009	080-22873151/ 22871472 09449843137	080-22871950/ 22201813	drpvasudevarao@rediffmail.com

Consignee	***Address***	***Telephone***	***Fax***	***E-mail***
Maharashtra	Joint Director Health Services (Mal, Fil & Water Borne Diseases) Arogya Bhavan Opp. Vishrantwadi Police Station Yerwada, Pune-411 006 Maharashtra	020-26696894 020-26693922 020-26693550 020-26694893	020-26693651 020-26693688	jtdhscell@rediffmail.com jtdhstech@yahoo.co.in
Gujarat	Joint Director (Mal. & Fil.) Commissionarate of Health Services & Medical Education Dr. Jivraj Mehta Bhavan Block No. 5, Gandhinagar-382 010 Gujarat	079-23253294 079-23253293 09979881433	079-23253295	jtdirmf@gujarat.gov.in jtdirmf@yahoo.co.in george13863@yahoo.com

SECTION IV.

TECHNICAL SPECIFICATIONS

PART 1

TECHNICAL SPECIFICATIONS OF Amphotericin- B INJECTION FOR KALA-AZAR under NVBDCP

Amphotericin –B Injection should comply with the standare given in IP.

Amphotericin-B is a sterile freeze dried mixture of Amphotericin-B and dexycholate sodium with one or more buffering agents. It is filled in a sealed container.

The injection is constituted by dissolving and contents of the sealed container in the requisite amount of sterile Water for injection, immediately before use.

The constituted solution complies with the requirements for Clarity of solution and Particulate Matter stated under Parenteral preparations (injections).

Storage: The constituted solution should be used immediately after preparation but, in any case within the period recommended by the manufacture.

Amphotericin-B injection contains not less than 90.0 percent and not more than 120.0 per cent of the stated amount of Amphotericin-B $C_{47}H_{73}NO_{17}$.

The contents of the sealed container comply with the requirements stated under Parenteral Preparations (powder for injection) and with the following requirements.

Usual Strength: 50mg per ml.

Tests:

pH (2.4.24).7.2 to 8.0 determined in a solution containing 10 mg per ml of Amphotericin B.

Bacterial Endotoxins (2.2.3) Not more than 5.0 Endotoxin unit per mg of Amphotericin B. for products used or labelled for intrathecal injection, not more than 0.9 Endotoxin unit per mg.

Loss on drying (2.4.19) Not more than 8.0 per cent, determined on 0.1 g by drying in an oven at 60º at a pressure not exceeding 0.7 kPa.

Assay: Determine by the microbiological assay of antibiotics, Method A (2.2.10) on a solution prepared in the following manner.

Mix the contents of 10 containers, dissolve in dimethylformamide. Express the results in mg per vial, taking each 1000 units found to be equivalent to 1 mg of Amphotericin-B.

Storage: Store in tightly closed container between 2º to 8º, protected from light

Labeling: Label it to state that it is intended for use by intravenous infusion to hospitalized patients only, and that the solution be protected from light during administration.

Shelf-life: 24 months, at least 3/4th of the shelf life must remain at the time of shipment. To the consignee. The supplier will provide manufacturer‟s stability test data substantiating the claimed shelf life in the offered package.

Labelling: The label on each ampoule shall conform to the requirements of Rule 96 of Drugs & Cosmetics Act and Indian Pharmacopoeia and shall appear in the language of English.

All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition, all labels shall state the name of the manufacturer, manufacturing license number, address of manufacturer, lot number, and expiry date. The label should bear a statement "the preparation is intended for intravenous injection only"

Labelling for secondary packaging: A label must be affixed either on the top and/or front surface of the secondary package. It should indicate the number of ampoules, the name of the manufacturer, batch number, date of manufacture, date of expiry, and storage conditions. The label should bear a statement "the preparation is intended for intravenous injection only".

Additional Labelling: All the containers and other outer containers shall be marked with the statement **"NVBDCP SUPPLY NOT FOR SALE"** in English. All labels on containers i.e. vials, cartons etc. should be marked with the statement **"NVBDCP SUPPLY NOT FOR SALE"** in bold red letters in English.

Printed Material: Information sheets, printed in English, shall be included in each secondary package and shall include information, such as, administration, adverse effects, contraindications, precautions and storage conditions.

Quality Assurance:

Compliance: The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per WHO-GMP requirements.

Evidence: The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.

The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment. The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment.

The test data for raw materials including glass container, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser‟s representatives when requested.

Packing:

Primary Package: IP Type 1 amber coloured glass vial provided with compatible elastomer closure and crimp- on aluminium seal and plastic overcap. Each vial shall contain 50 mg of Amphoterecin B injection. Sufficient overages are added as per Pharmacopoeia so that 50 mg of extractable quantity can be achieved.

Secondary Package: 15 vials should be packed suitably segregated from each other by providing honeycomb partitioning with proper cushioning in boxes for easy handling, transport and distribution. The box may contain 15 vials. It shall be fabricated from Millboard/ grey board/ cardboard with a minimum of bursting strength of 400gsm.

Sterile Water for Injections:

Description: A clear, colourless solution; odourless, free from added substances. Each ampoule shall contain 05 ml of Sterile Water of Injection. The quality of Sterile Water for Injection should conform to the requirements of IP. If not mentioned in IP then other Pharmacopoeia of equivalent accuracy in case of international transactions may be followed.

Storage: Store in a single dose container.

Shelf-life: At least 5/6th of the shelf life must remain at the time of shipment. The supplier will provide manufacturer"s stability test data substantiating the claimed shelf life in the proposed package.

Labelling: The label on each ampoule shall conform to the requirements of Rule 96 of Drugs & Cosmetics Act andI.P and shall appear in the language of English/Hindi.

All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in IP, all labels shall state the name of the manufacturer, manufacturing license number, address of manufacturer, lot number, and expiry date.

Labelling for secondary packaging: A label must be affixed either on the top and/or front surface of the secondary package. It should indicate the number of vials, the name of the manufacturer, batch number, date of manufacture, date of expiry, and storage conditions.

Quality Assurance:

Compliance: The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per cGMP included in Schedule M. In case of International transaction WHO GMP requirements shall be applicable.

Evidence: The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.

The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.

The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment**.**

The test data for raw materials including water for injection, glass container, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser"s representatives when requested.

Details of samples lifted for testing (such as Millboard/Greyboard boxes, batch no. etc;) should be pasted on the packing of 5 Ply Shipper and records to this effect to be made available to the purchaser

Packing:

Primary Package:

IP Type 1 clear plain glass ampoules or PE ampoule based on FFS technology. Each ampoule shall contain 05 ml of sterile water for injection. The ampoule should be sufficiently transparent to permit visual inspection of the contents.

Secondary Package:

The ampoules should be packed suitably segregated from each other by providing honeycomb partitioning with proper cushioning in boxes for easy handling, transport and distribution. The box may contain 15 ampoules. It shall be fabricated from Millboard/ grey board/ cardboard with a minimum of bursting strength of 400gsm.

Disposable Syringe and Disposable Needle:

Description (Disposable Syringe): Disposable Syringes are Sterile Hypodermic Syringes for Single Use and are fabricated from virgin plastic. They shall conform to the standards given in IS 10258:2002. These are medical device intended for immediate use for administration of injectable preparations. They are supplied sterile and pyrogen – free and not to be re-sterilised or reused.

The plastics and elastomer materials (polypropylene and polyethylene) of which the barrel and piston are made comply with the relevant specifications issued by BIS. The Syringes comply with the following standards regarding Dimensions including dead volume.

Capacity of the Syringe ml	Tolerance eq. or ex. to cap.	Tolerance < half of cap.	Max. Dead Vol. ml	Length 0f long Graduation Mark, mm	Overall length of scale, mm	Scale Interval ml	Increment. Between Graduation lines ml
05	+_4% of expelled vol	+_1.5% nominal Cap, +1% of expelled vol	0.075	8	36	0.50	1

Polydimethylsiloxane (Silicone Oil) is applied to the internal walls of the barrel to assist in the smooth operation of the syringe but no excess be ensured capable of contaminating the contents at the time of use.

Description (Disposable Needles): Sterile Hypodermic Needles for Single Use

comprise of a length of hypodermic grade stainless steel tube connected to a hub that is designed to mate with a syringe or an IV set. They shall conform to the standards given in IS10654:2002. The other end of the tube is sharpened at the tip as per IS requirements. The tube is covered with a shield made from polypropylene. The hub fabricated from poly propylene is colour coded as per the requirements of ISO 6009. The union of the hub and needle tube is carried out with epoxy adhesive. This medical device in conjunction with Syringe is intended for immediate use for administration of injectable preparations. They are supplied sterile and pyrogen – free and not to be re-sterilised or reused.

The Hypodermic needles shall comply with the following standards regarding Dimensions:

Needle Gauge	Colour of the hub	Nominal Length of the tube mm	Tolerance In length mm	Nominal outside diameter Of needle mm	Diameter of stylet for normal walled tubing mm
23	Blue	25	+ 1, -2	0.6	0.25

Storage: Disposable Syringes and Disposable Needles should be stored in a clean, cool, dry and adequately ventilated place.

Shelf-life: At least 5/6th of the shelf life must remain at the time of shipment. The supplier will provide manufacturer' stability test data substantiating the claimed shelf life in the proposed package.

Labelling: The label on each strip shall conform to the requirements of I.P and shall appear in the language of English/Hindi.

All labeling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in Drugs & Cosmetic Act 1940 and rules there under, following information should be available:

- A description of the syringe including the capacity/ A description of the Needle including the Gauge and the nominal length
- The word Sterile"
- That the syringe/needle is for single use only
- A solvent incompatibility
- The batch number
- Name and address of the manufacturer
- Date of Manufacture and Date of Expiry
- Warning that the syringe is not to be used if the packaging is damaged or sterility protector is loose
- CE marking
- ISO symbol for "do not re-use"

Labelling for secondary packaging:

Secondary Package: A label must be affixed either on the top and/or front surface of the secondary package. It should indicate:

- A description of the syringe including the capacity and the type of nozzle/ A description of the needle including the gauze and the nominal length

- Quantity of primary packages
- The word „Sterile‟
- That the syringe is for single use only
- The batch number
- The date (month and year) of sterilization
- Name and address of the manufacturer
- Date of Manufacture and Date of Expiry
- Information for handling, storage and transportation

Quality Assurance:

Compliance: The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per GMP included in Schedule M - III. and (f) the product should conform to ISO 13485.

Evidence: The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned. The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.

The Supplier shall provide a documentary evidence that the sterilization of the syringes has been carried out by validated sterilization procedures (with appropriate controls and recording devices) in case it has been carried out in their premises. If the facilities of other institution is used for sterilization, the approval of the licensing authority and documentary evidence for validated sterilization procedure should be made available.

The supplier shall provide a documentary evidence that the inks, glues and adhesives for the marking on the package and on the assembly of the syringe and its package (Wherever necessary) do not migrate across the walls.

The supplier shall provide documentary evidence in regards to bio-compatibility of the device as per the requirements given in “Biological Evaluation of Medical Devices” IS 12572.

The supplier shall provide a copy of CE certificate.

The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.

The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser‟s representatives when requested.

A. Packing:

Primary Package: Each syringe and needle shall be packed and sealed separately in a primary container. The material of each container should not have detrimental effects on the contents. The material and design should be such as to ensure:

a) The maintenance of sterility under dry, clean and adequately ventilated storage conditions;

b) The minimum risk of contamination of the contents during opening of the container and removal of the contents;
c) Adequate protection of the contents during normal handling, transit and storage;
d) That once opened, the container cannot be easily resealed, and it should be obvious that the container has been opened.
e) Paper-PVC lister:
f) PVC Film: Transparent, clear, food grade, blister forming PVC film, film gauge-200 microns, PE coating: 25 microns.
g) Hard tempered Blister paper, VMCH coated, Thickness: 0.025mm

Secondary Package: The primary package should be packed in boxes for easy handling, transport and distribution. The box may contain --- primary packages. It shall be fabricated from Millboard/ grey board/ cardboard with a minimum of bursting strength of 400gsm.

B. Inspection: The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier‟s factory and/or warehouse at a mutually agreeable time prior to the shipment of the product. Details of samples lifted for testing (such as Millboard/Greyboard boxes, batch no. etc;) should be pasted on the packing of 5 Ply

Shipper and records to this effect to be made available to the purchaser

C. Testing: The Purchaser may cause independent laboratory testing to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser‟s choice if suitably equipped and qualified to conduct quality assurance tests on the product.

D. Labelling on Shipper Package: The external surface of insulated packages should be either white or in the natural color of corrugated carton.

The labels on tertiary packaging must be attached to at least two sides. The label should include the name of the product, the number of secondary package (boxes) of Amphoterecin-B Injections and Disposable Syringes plus Disposable Needles, the name of the manufacturer, Master batch number, date of manufacture, and date of expiry.

The label shall include bar code and be tear proof to be pasted on smooth surface to enable it to be read by bar code reader.

E. Packing for Shipper Package: The boxes shall be packed in weather resistant triple walled insulated corrugated 5-ply cartons, each ply having strength of minimum150gsm. It should be fabricated from virgin quality „A‟ grade material. The overalldimension of the carton should be such that the product does not get damaged during transportation and storage. Each shipper package shall contain 50 secondary packs of Amphotericin-B for Injection, 50 seconday packs of Sterile water for injections and 50 secondary packs of Disposable syringe and Disposable Needle.

F. Qualification of the Manufacturer: The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical

product is licensed to manufacture these products. The manufacturing facility must conform to WHO-GMP standards. In case of medical devices the manufacturing facility must conform to the standards given in Schedule M-III of Drugs & Cosmetics Act and ISO
13485.

G. **Recalls:** If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

H. **Colour Coding:** The labels on secondary packing, tertiary and shipper package shall be identified by WHITE background.

I. **Bar Coding:** Bar code shall be used to track down the product. It shall be printed on the label of Shipper containing

1) Product identification (GTIN 14) using application identifier (01)
2) Expiry Date in YYMMDD format & using application identifier (17)
3) Master batch number using application identifier (10)

Complete details on GS1 standards along with technical guidelines can be downloaded from www.gs 1india.org or www.gs1.org

J. **Markings:** All containers and invoices must bear the name of the product, expiry dates of and appropriate storage conditions.

Inner boxes: The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser:

- Generic name of the product
- Strength in terms of active ingredient in mg per ml wherever required
- Names and concentrations of the adjuvant/ preservative added wherever required
- Manufacturer"s name and registered address
- Manufacturer"s License number
- Lot or batch number
- Number of vials/ampoules/Syringes with needles contained in box
- Date of manufacture (month and year)
- Expiration date (month and year)
- Instructions for storage and handling
- Place of manufacture (Made in_____)

Exterior Shipping Cartons: The following information shall be stenciled or labelled on theexteri or shipping cartons on all four sides in bold letters at least Ariel font size 14 with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name of the product
- Strength in terms of active ingredient in mg per ml

- Names and concentrations of the adjuvant/ preservative added
- Lot or batch number
- Date of manufacture (month and year)
- Expiration date (month and year)
- Manufacturer‟s name and registered address
- Manufacturer‟s national registration number
- Destination country license or registration number

Consignee‟s address and emergency phone number including mobile number

- Destination airport
- Contract number
- Number of ampoules/Syringes-needles pouches/boxes contained in the carton
- Gross weight of each carton (in kg)
- Carton containing ------- secondary packages
- Instructions for storage and handling
- Place of manufacture (Made in_____)

K. **Documentation:** Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the product being supplied.

Advance notice of arrival and advance shipping documentation: Copies of the documentation for the goods to be shipped must be sent at least seven days in advance of arrival of the shipment. In the case of an individual contract for a specific destination that requires a longer period of advance notice, a longer period should apply. The consignee(s) shall be intimated well in advance by registered letter/e-mail/ telephone, so that the products are collected from the airport immediately after arrival. The documentation must include the following:

- Pre-advice defined by the Purchaser
- Airway bill (AWB);
- Supplier‟s invoice;
- Packing list;
- Lot release certificate (LRC) as per the requirements issued by the national regulatory authority (NRA) of the country of manufacture for each lot and
- Any other document, certificate or instruction specified in the individual order.

The documents shall be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignee, the Purchaser, and any other parties specified in the individual contract.

The pre-advice must contain the following information:

- Purchase order reference;
- Consignee requisition reference;
- Number of packages and gross weight (in kilograms).
- Value of shipment (in Indian Rupees and US $);
- AWB and flight number(s);

- Date and time for place of departure, transit (if applicable), and arrival;
- Instructions for collection;
- Any other information specified in the individual contract must also be included for the consignee.

The following information shall be stated on the airway bill:

- Consignee‟s name, address, tel. number (including mobile no.) and e-mail ID.
- Purchase order reference;
- Consignee‟s requisition reference;
- Instructions to: “Telephone consignee upon arrival (repeat telephone number);

L. Dispatch: Shipments should be scheduled to arrive outside weekends and/or public holidays in the recipient country and airline bookings should be made well ahead of the date of departure.

Technical Specifications for Artesunate Injection Kit

A. Specific requirements

Artesunate Injection Kit consists of a vial of Artesunate Injection; an ampoule of 5% Sodium Bicarbonate Injection; an ampoule of Sodium Chloride Solution and Disposable Syringe along with Disposable needle. The individual items contained in the product shall be currently registered in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The individual items contained in the product shall also be currently registered in India and shall meet all the requirements of the licensing authority in India.

Artesunate Injection:

Description:

Artesunate Injection contains a sterile powder containing Artesunate. Each vial shall contain -Artesunate IP 60 mgArtesunate Injection complies with WHO working document QAS/10.365/FINAL May 2011 (Adopted text for addition to The International Pharmacopoeia) The powder for injection and the reconstituted injection comply with the monograph for "Parenteral reparations" included in the latest edition of International Pharmacopoeia.

The injection is constituted by dissolving the contents of the sealed container in the requisite amount of Sterile Water for Injections, immediately before use.

The quality of Artesunate injection should conform to the requirements of IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

Labelling:

The label on each vial shall conform to the requirements of I.P and shall appear in the language of English/Hindi. All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in IP, all labels shall state the quantity of Artesunate contained in the sealed container, the name of the manufacturer, manufacturing license number, address of manufacturer, lot number, and expiry date. The label shall conform to the requirements of Rule 96 of Drugs & Cosmetic Act.

Packing:

Primary Package:
5 ml Vial (IP type 1 clear)(Containing Artesunate Powder for injection) closed with 20 mm Bromobutyl Rubber Plug and Sealed with flip off seal and plastic overcap.

Sodium Bicarbonate Injection:

Description:

A clear, colourless solution.Each ampoule shall contain 1 ml of Sodium Bicarbonate Injection(5%W/v).

The quality of Sodium Bicarbonate and Sterile Water for Injection should conform to the requirements of IP. If not mentioned in IP then other Pharmacopoeia of equivalent accuracy in case of international transactions may be followed.

Labelling:

The label on each ampoule shall conform to the requirements of I.P and shall appear in the language of English/Hindi.

All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in IP, all labels shall state the name of the manufacturer, manufacturing license number, address of manufacturer, lot number, and expiry date.

Packing:

Primary Package:

IP Type 1 clear plain glass ampoules. Each ampoule shall contain 1 ml of Sodium Bicarbonate injection (5%w/v). The ampoule should be sufficiently transparent to permit visual inspection of the contents.

Sodium Chloride Injection:

Description:

A clear, colourless solution.Each ampoule shall contain 5 ml of Sodium Chloride Injection (0.9%W/v).

The quality of Sodium Chloride and Sterile Water for Injection should conform to the requirements of IP. If not mentioned in IP then other Pharmacopoeia of equivalent accuracy in case of international transactions may be followed.

Labelling:

The label on each ampoule shall conform to the requirements of I.P and shall appear in the language of English/Hindi.

All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in IP, all labels shall state the name of the manufacturer, manufacturing license number, address of manufacturer, lot number, and expiry date.

Packing:Primary Package:

IP Type 1 clear plain glass/FFS ampoule. Each ampoule shall contain 5 ml of Sodium Chloride injection (0.9%w/v). The ampoule should be sufficiently transparent to permit visual inspection of the contents.

Secondary Package for Atresunate Injection + Sodium bicarbonate Injection + Sodium Chloride Injection:

One vial of Artesunate Injection, one ampoule of Sodium bicarbonate Injection and one ampoule of Sodium Chloride Injection are packed in PVC blisters sealed, thermo-formated trays having high rigidity and sufficient impact strength to provide break resistance packaging.

The tray along with **Instructions for reconstitution and administration of Artesunate Injection** should be packed in a box for easy handling, transport and distribution. It shall be fabricated from Millboard/ grey board/ cardboard with a minimum of bursting strength of 300gsm.

Labelling for secondary packaging:
A label must be affixed either on the top and/or front surface of the secondary package. It should indicate number of boxes of Artesunate injection + Sodium Bicarbonate Injection + Sodium Chloride Injection. Separately the name of the manufacturer, batch number, date of manufacture, date of expiry of Artesunate Injection, Sodium Bicarbonate Injection and Sodium Chloride Injection should be given. The master batch number of the Kit along with Date of Expiry should be given. The label should also give Storage requirements. The label shall conform to the requirements of Rule 96 of Drugs & Cosmetic Act.

Quality Assurance:

Compliance:

The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per WHO GMP requirements.

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.

The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.

The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment**.**

The Supplier shall provide to the Purchaser a copy of the approval on demand of each source material, constituent material and component for each lot intended for shipment.

The test data for raw materials including water for injection, glass container, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser"s representatives when requested.

Details of samples lifted for testing (such as Millboard/Greyboard boxes, batch no. etc;) should be pasted on the packing of 5 Ply Shipper and records to this effect to be made available to the purchaser

Disposable Syringe and Disposable Needle:

Description (Disposable Syringe):

Disposable Syringes are Sterile Hypodermic Syringes for Single Use and are fabricated from **virgin** plastic. They shall conform to the standards given in IS 10258:2002. These are medical device intended for immediate use for administration of injectable preparations. They are supplied sterile and pyrogen – free and not to be re-sterilised or reused. The plastics and elastomer materials (**polypropylene and polyethylene**) of which the barrel and piston are made comply with the relevant specifications issued by BIS. The Syringes comply with the following standards regarding Dimensions including dead volume.

Capacity of the Syringe ml	**Tolerance eq. or ex. to cap.**	**Tolerance < half of cap.**	**Max. Dead Vol. ml**	**Length of long Graduation Mark, mm**	**Overall length of scale, mm**	**Scale Interval ml**	**Increment. Between Graduation lines**
05	+_4% of expelled vol	+_1.5% nominal Cap, +1% of expelled Vol.	0.075	8	36	0.50	1

Polydimethylsiloxane (Silicone Oil) is applied to the internal walls of the barrel to assist in the smooth operation of the syringe but no excess be ensured capable of contaminating the contents at the time of use.

Description (Disposable Needles):

Sterile Hypodermic Needles for Single Use comprise of a length of hypodermic grade stainless steel tube connected to a hub that is designed to mate with a syringe or an IV set. They shall conform to the standards given in IS 10654:2002. The other end of the tube is sharpened at the tip as per IS requirements. The tube is covered with a shield made from polypropylene. The hub fabricated from poly propylene is colour coded as per the requirements of ISO 6009. The union of the hub and needle tube is carried out with epoxy adhesive. This medical device in conjunction with Syringe is intended for immediate use for administration of injectable preparations.

They are supplied sterile and pyrogen – free and not to be re-sterilised or reused.

The Hypodermic needles shall comply with the following standards regarding Dimensions:

Needle Gauge	**Colour of the hub**	**Nominal Length of the tube mm**	**Tolerance In length**	**Nominal outside diameter Of needle**	**Diameter of stylet for normal walled**
23	Blue	25	+ 1, -2	0.6	0.25

Labelling:

The label on each strip shall conform to the requirements of I.P and shall appear in the language of English/Hindi.

All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in Drugs & Cosmetic Act 1940 and rules there under, following information should be available:

A description of the syringe including the capacity/ A description of the Needle including the Gauge and the nominal length
The word „Sterile"
That the syringe/needle is for single use only
A solvent incompatibility
The batch number
Name and address of the manufacturer
Date of Manufacture and Date of Expiry
Warning that the syringe is not to be used if the packaging is damaged or sterility protector is loose
CE marking
ISO symbol for "do not re-use"

Labelling for secondary

packaging: Secondary Package:

A label must be affixed either on the top and/or front surface of the secondary package. It should indicate:

A description of the syringe including the capacity and the type of nozzle/ A description of the needle including the gauze and the nominal length
Quantity of primary packages
The word „Sterile"
That the syringe is for single use only
The batch number
The date (month and year) of sterilization

Name and address of the manufacturer
Date of Manufacture and Date of Expiry
Information for handling, storage and transportation

Quality Assurance:

Compliance:

The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per cGMP included in Schedule M - III. (f) the product is WHO pre-qualified and (g) the product should conform to ISO 13485.

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.

The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.

The Supplier shall provide a documentary evidence that the sterilization of the syringes has been carried out by validated sterilization procedures (with appropriate controls and recording devices) in case it has been carried out in their premises. If the facilities of other institution is used for sterilization, the approval of the licensing authority and documentary evidence for validated sterilization procedure should be made available.

The supplier shall provide a documentary evidence that the inks, glues and adhesives for the marking on the package and on the assembly of the syringe and its package (Wherever necessary) do not migrate across the walls.

The supplier shall provide documentary evidence in regards to bio- comapatibility of the device as per the requirements given in “Biological Evaluation of Medical Devices” IS 12572.

The supplier shall provide a certificate of analysis of Polydimethylsiloxane (used for lubrication) conforming to the requirements of IP. The

supplier shall provide a copy of CE certificate.

The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment

Packing:

Primary Package:

Each syringe and needle shall be packed and sealed separately in a primary container. The material of each container should not have detrimental effects on the contents. The material and design should be such as to ensure:

a) The maintenance of sterility under dry, clean and adequately ventilated storage conditions;
b) The minimum risk of contamination of the contents during opening of the container and removal of the contents;
c) Adequate protection of the contents during normal handling, transit and storage;
d) That once opened, the container cannot be easily resealed, and it should be obvious that the container has been opened.

Paper-PVC Blister:

- PVC Film: Transparent, clear, food grade, blister forming PVC film, film gauge- 200microns, PE coating: 25 microns.
- Hard tempered Blister paper, VMCH coated, Thickness: 0.025mm

Secondary Package:

The primary package should be packed in boxes for easy handling, transport and distribution. The box may contain --- primary packages. It shall be fabricated from Millboard/ grey board/ cardboard with a minimum of bursting strength of 400gsm.

B. Inspection:

The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier‟s factory and/or warehouse at a mutually agreeable time prior to the shipment of the product.

C. Testing::

The Purchaser may cause independent laboratory testing to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser‟s choice if suitably equipped and qualified to conduct quality assurance tests on the product.

D. Labelling on Shipper Package:

The external surface of insulated packages should be either white or in the natural color of corrugated carton.

The labels on tertiary packaging must be attached to at least two sides. The label

should include the name of the product, the number of secondary package (boxes) of Artesunate Injection + Sodium Bicarbonate Injection + Sodium Chloride Injection and Disposable Syringes plus Disposable Needles, the name of the manufacturer, Mater batch number and date of

expiry.

The label shall include bar code and be tear proof to be pasted on smooth surface to enable it to be read by bar code reader.

E. Packing for Shipper Package:

The secondary packages of Artesunate Injection + Sodium Bicarbonate Injection + Sodium Chloride Injection and that of Syringes + needles shall be packed in weather resistant triple walled insulated corrugated 5-ply cartons, each ply having strength of minimum 150gsm. It should be fabricated from virgin quality „A" grade material. Burst factor of individual ply should be not less than 22. GSM of the shipper should be not less than 13 Kg/cm^2 . Overall dimensions of the carton should be such that the product does not get damaged during transportation and storage.

F. Shelf Life of Artesunate Injection Kit:

24 months, At least $3/4^{th}$ of the shelf life must remain at the time of shipment. The supplier will provide manufacturer"s stability test data substantiating the claimed shelf life in the offered package

The expiry date of the Artesunate Injection Kit shall be the same as that of Artesunate Injection being the constituent of product with the shortest shelf life.

G. Numbering of shipper packaging:

All boxes should be numbered consecutively. Shipping documents should be included in the box labelled number 1 (consignee wise),

H. Qualification of the Manufacturer:

The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to WHO-GMP standards. In case of medical devices the manufacturing facility must conform to the standards given in ISO 13485 and Schedule M-III of Drugs & Cosmetic Act.

I. Recalls:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

J. Model Inserts:

An insert containing information in regards to adverse drug reactions and precautions (to be observed while taking the drug) of all the drugs included in the product should form part of each secondary pack.

K. Colour Coding:

The labels on secondary packing, and shipper package shall be identified by WHITE background.

L. Bar Coding:

Bar code shall be used to track down the product. It shall be printed on the label of Shipper containing

1) Product identification(GTIN 14) using application identifier (01)
2) Expiry Date in YYMMDD format & using application identifier (17)
3) Master batch number using application identifier (10)

Complete details on GS1 standards along with technical guidelines can be downloaded from www.gs 1india.org or www.gs1.org

M. Documentation

Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the product being supplied.

Advance notice of arrival and advance shipping documentation:

Copies of the documentation for the goods to be shipped must be sent at least seven days in advance of arrival of the shipment. In the case of an individual contract for a specific destination that requires a longer period of advance notice, a longer period should apply. The consignee(s) shall be intimated well in advance by registered letter/e-mail/ telephone, so that the products are collected from the airport immediately after arrival.

The documentation must include the following:

Pre-advice defined by the Purchaser
Airway bill (AWB);
Supplier‟s invoice;
Packing list;
Lot release certificate (LRC) as per the requirements issued by the national regulatory authority (NRA) of the country of manufacture for each lot and
Any other document, certificate or instruction specified in the individual order.

The documents shall be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignee, the Purchaser, and any other parties specified in the individual contract.

The pre-advice must contain the following information:

Purchase order reference;
Consignee requisition reference;
Number of packages and gross weight (in kilograms).
Value of shipment (in Indian Rupees and US $);
AWB and flight number(s);
Date and time for place of departure, transit (if applicable), and arrival;

Instructions for collection;
Any other information specified in the individual contract must also be included for the consignee.

The following information shall be stated on the airway bill:

Consignee‟s name, address, telephone number (including mobile no.) and e-mail ID.
Purchase order reference;
Consignee‟s requisition reference;

• Instructions to: “Telephone consignee upon arrival *(repeat telephone number);*

N. Dispatch:

Shipments should be scheduled to arrive outside weekends and/or public holidays in the country and airline bookings should be made well ahead of the date of departure

Technical Specifications for Paromomycin IM Injection for Kala Azar

Description of Store: Parammomycin IM injection 1*2 ml ampoules containing 375 mg of Paromomycin per ml.

Shelf Life: Minimum 2years whne stored below 30 C and protected from light.

Special precautions for storage:
Store below 30 C. Protect form lisght. Do not freeze.
DO NOT STORE partially used ampoules for futre patient use.

Nature and Content of Container:
2 ml Type 1 amber glass ampoules, supplied in packs of 10 ampoules.

Instructions fo Use and Handling and Disposal:
For single use only. Any unsused paromomycin from opened ampoules should be discarded.

Labelling /Printing:

- **On the injection of Ampoule**

  - Name of injection product
  - Name of manufacture with address
  - IM use only
  - License No.
  - Lot No. and Batch No.
  - Manufacturing and expiry date
  - The contents of injection per ml
  - Govt. Of India Supply Not for Sale
    (Preferably in red colour, or in any contrast colour)

- **On the Primary Packing of sliding Cardbox box**

  - Name of injection product
  - Name of manufacture with address
  - IM use only
  - License No.
  - Lot No. and Batch No.
  - Manufacturing and expiry date
  - The contents of injection per ml
  - Govt. Of India Supply Not for Sale
    (Preferably in red colour, or in any contrast colour)

  - Dosage-Adult/Children
  - Indications for use

- Adverse effect/Side effects
- Precautions
- Storage Condition

(C) On the Secondary Packing/Inner Carton and Outer shipper of Corrugated Box

- Name of injection product
- Name of manufacture with address
- IM use only
- License No.
- Lot No. and Batch No.
- Manufacturing and expiry date
- The contents of the container
- Govt. Of India Supply Not for Sale
  (Preferably in red colour, or in any contrast colour)
- Precaution for transportation
- Storage condition
- The box should be packed with thermocol material to prevent breakage.

Good Manufacturing Practices (GMP): The manufacturing facility must confirm to GMP as per Schedule ‘M’ of the Drugs & Cosmetic Act.

Product should be COPP complying.

PART 2

CHECK LIST FOR TECHNICAL SPECIFICATIONS

Section IV Techncial Specifications

PART A

For Each clause of Technical Specifications the bidder shall prepare a table below:

S.No.	Technical Specification (Amphotericin –B Injection)	Compliance Yes/No	Page in the bid submitted where documentary evidence is enclosed
1)	Amphotericin –B Injection should comply with the standare given in IP. Amphotericin-B is a sterile freeze dried mixture of Amphotericin-B and dexycholate sodium with one or more buffering agents. It is filled in a sealed container. The injection is constituted by dissolving and contents of the sealed container in the requisite amount of sterile Water for injection, immediately before use. The constituted solution complies with the requirements for Clarity of solution and Particulate Matter stated under Parenteral preparations (injections).		
2)	**Storage:** The constituted solution should be used immediately after preparation but, in any case within the period recommended by the manufacture. Amphotericin-B injection contains not less than 90.0 percent and not more than 120.0 per cent of the stated amount of Amphotericin-B C47H73NO17. The contents of the sealed container comply with the requirements stated under Parenteral Preparations (powder for injection) and with the following requirements.		
3)	**Usual Strength:** 50mg per ml.		
4)	**Tests:** pH (2.4.24).7.2 to 8.0 determined in a solution containing 10 mg per ml of Amphotericin B.		
5)	**Bacterial Endotoxins (2.2.3)** Not more than 5.0 Endotoxin unit per mg of Amphotericin B. for products used or labelled for intrathecal injection, not more than 0.9 Endotoxin unit per mg.		
6)	**Loss on drying (2.4.19)** Not more than 8.0 per cent, determined on 0.1 g by drying in an oven at 60º at a pressure not exceeding 0.7 kPa.		
7)	**Assay:** Determine by the microbiological assay of antibiotics, Method A (2.2.10) on a solution prepared in the following manner. Mix the contents of 10 containers, dissolve in dimethylformamide. Express the results in mg per vial, taking each 1000 units found to be equivalent to 1 mg of Amphotericin-B.		
8)	**Storage:** Store in tightly closed container between 2º to 8º, protected from light .		
9)	**Labeling**: Label it to state that it is intended for use by intravenous infusion to hospitalized patients only, and that the solution be protected from light during administration.		
10)	**Shelf-life:** 24 months, at least 3/4th of the shelf life must remain at the time of shipment. To the consignee The supplier will provide manufacturer‟s stability test data substantiating the claimed shelf life in the offered package.		
11)	**Labelling:** The label on each ampoule shall conform to the requirements of Rule 96 of Drugs & Cosmetics Act and Indian Pharmacopoeia and shall appear in the language of English.		

Section IV Techncial Specifications

S.No.	Technical Specification (Amphotericin –B Injection)	Compliance Yes/No	Page in the bid submitted where documentary evidence is enclosed
	All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition, all labels shall state the name of the manufacturer, manufacturing license number, address of manufacturer, lot number, and expiry date. The label should bear a statement "the preparation is intended for intravenous injection only"		
12)	**Labelling for secondary packaging:** A label must be affixed either on the top and/or front surface of the secondary package. It should indicate the number of ampoules, the name of the manufacturer, batch number, date of manufacture, date of expiry, and storage conditions. The label should bear a statement "the preparation is intended for intravenous injection only".		
13)	**Additional Labelling:** All the containers and other outer containers shall be marked with the statement "**NVBDCP SUPPLY NOT FOR SALE**" in English. All labels on containers i.e. vials, cartons etc. should be marked with the statement "**NVBDCP SUPPLY NOT FOR SALE**" in bold red letters in English.		
14)	**Printed Material:** Information sheets, printed in English, shall be included in each secondary package and shall include information, such as, administration, adverse effects, contraindications, precautions and storage conditions.		
15)	**Quality Assurance:** **Compliance:** The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per WHO-GMP requirements.		
16)	**Evidence:** The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned. The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment. The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment. The test data for raw materials including glass container, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser‟s representatives when requested.		
17)	**Packing:** **Primary Package:** IP Type 1 amber coloured glass vial provided with compatible elastomer closure and crimp- on aluminium seal and plastic overcap. Each vial shall contain 50 mg of Amphoterecin B injection. Sufficient overages are added as per Pharmacopoeia so that 50 mg of extractable quantity can be achieved.		
18)	**Secondary Package:** 15 vials should be packed suitably segregated from each other by providing honeycomb partitioning with proper cushioning in boxes		

Section IV Techncial Specifications

S.No.	Technical Specification (Amphotericin –B Injection)	Compliance Yes/No	Page in the bid submitted where documentary evidence is enclosed
	for easy handling, transport and distribution. The box may contain 15 vials. It shall be fabricated from Millboard/ grey board/ cardboard with a minimum of bursting strength of 400gsm.		
19)	**Sterile Water for Injections:** **Description:** A clear, colourless solution; odourless, free from added substances. Each ampoule shall contain 05 ml of Sterile Water of Injection. The quality of Sterile Water for Injection should conform to the requirements of IP. If not mentioned in IP then other Pharmacopoeia of equivalent accuracy in case of international transactions may be followed.		
20)	**Storage:** Store in a single dose container.		
21)	**Shelf-life:** At least 5/6th of the shelf life must remain at the time of shipment. The supplier will provide manufacturer‟s stability test data substantiating the claimed shelf life in the proposed package (minimum shelf life 36 months).		
22)	**Labelling:** The label on each ampoule shall conform to the requirements of Rule 96 of Drugs & Cosmetics Act andI.P and shall appear in the language of English/Hindi. All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in IP, all labels shall state the name of the manufacturer, manufacturing license number, address of manufacturer, lot number, and expiry date.		
23)	**Labeling for secondary packaging**: A label must be affixed either on the top and/or front surface of the secondary package. It should indicate the number of vials, the name of the manufacturer, batch number, date of manufacture, date of expiry, and storage conditions.		
24)	**Quality Assurance:** **Compliance:** The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per cGMP included in Schedule M. In case of International transaction WHO GMP requirements shall be applicable.		
25)	**Evidence:** The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned. The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment. The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.		

<table>
<tr><th>S.No.</th><th>Technical Specification (Amphotericin –B Injection)</th><th>Compliance

Yes/No</th><th>Page in the bid submitted where documentary evidence is enclosed</th></tr>
<tr><td></td><td>The test data for raw materials including water for injection, glass container, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser’s representatives when requested.

Details of samples lifted for testing (such as Millboard/Greyboard boxes, batch no. etc;) should be pasted on the packing of 5 Ply Shipper and records to this effect to be made available to the purchaser.</td><td></td><td></td></tr>
<tr><td>26)</td><td>Packing:
Primary Package: IP Type 1 clear plain glass ampoules or PE ampoule based on FFS technology. Each ampoule shall contain 05 ml of sterile water for injection. The ampoule should be sufficiently transparent to permit visual inspection of the contents.</td><td></td><td></td></tr>
<tr><td>27)</td><td>Secondary Package:
The ampoules should be packed suitably segregated from each other by providing honeycomb partitioning with proper cushioning in boxes for easy handling, transport and distribution. The box may contain 15 ampoules. It shall be fabricated from Millboard/ grey board/ cardboard with a minimum of bursting strength of 400gsm.</td><td></td><td></td></tr>
<tr><td>28)</td><td>Disposable Syringe and Disposable Needle:
Description (Disposable Syringe): Disposable Syringes are Sterile Hypodermic Syringes for Single Use and are fabricated from virgin plastic. They shall conform to the standards given in IS 10258:2002. These are medical device intended for immediate use for administration of injectable preparations. They are supplied sterile and pyrogen – free and not to be re-sterilised or reused.

The plastics and elastomer materials (polypropylene and polyethylene) of which the barrel and piston are made comply with the relevant specifications issued by BIS. The Syringes comply with the following standards regarding Dimensions including dead volume.

<table>
<tr><td>Capacity of the Syringe

ml</td><td>Tolerance eq. or ex. to cap.</td><td>Tolerance < half of cap.</td><td>Max. Dead Vol.

ml</td><td>Length 0f long Graduation
Ma</td><td>Overall length of scale, mm</td><td>Scale Interval

ml</td><td>Increment. Between Graduation</td></tr>
</table>
</td><td></td><td></td></tr>
</table>

<table>
<tr><th>S.No.</th><th>Technical Specification (Amphotericin –B Injection)</th><th>Compliance

Yes/No</th><th>Page in the bid submitted where documentary evidence is enclosed</th></tr>
<tr><td></td><td>
<table>
<tr><td>05</td><td>+_4 % of expelled vol</td><td>+_1.5% nominal

Cap, +1% of expelled vol</td><td>0.075</td><td>8</td><td>36</td><td>0.50</td><td>1</td></tr>
</table>
Polydimethylsiloxane (Silicone Oil) is applied to the internal walls of the barrel to assist in the smooth operation of the syringe but no excess be ensured capable of contaminating the contents at the time of use.</td><td></td><td></td></tr>
<tr><td>29)</td><td>Description (Disposable Needles): Sterile Hypodermic Needles for Single Use comprise of a length of hypodermic grade stainless steel tube connected to a hub that is designed to mate with a syringe or an IV set. They shall conform to the standards given in IS
10654:2002. The other end of the tube is sharpened at the tip as per IS requirements. The tube is covered with a shield made from polypropylene. The hub fabricated from poly propylene is colour coded as per the requirements of ISO 6009. The union of the hub and needle tube is carried out with epoxy adhesive. This medical device in conjunction with Syringe is intended for immediate use for administration of injectable preparations. They are supplied sterile and pyrogen – free and not to be re-sterilised or reused.

The Hypodermic needles shall comply with the following standards regarding Dimensions:
<table>
<tr><td>Needle Gauge</td><td>Colour of the hub</td><td>Nominal Length of the tube mm</td><td>Tolerance In length mm</td><td>Nominal outside diameter Of needle mm</td><td>Diameter of stylet for normal walled</td></tr>
<tr><td>23</td><td>Blue</td><td>25</td><td>+ 1, -2</td><td>0.6</td><td>0.25</td></tr>
</table></td><td></td><td></td></tr>
<tr><td>30)</td><td>Storage: Disposable Syringes and Disposable Needles should be stored in a clean, cool, dry and adequately ventilated place.</td><td></td><td></td></tr>
<tr><td>31)</td><td>Shelf-life: At least 5/6th of the shelf life must remain at the time of shipment. The supplier will provide manufacturer‟s stability test data substantiating the claimed shelf life in the proposed package.</td><td></td><td></td></tr>
<tr><td>32)</td><td>Labeling: The label on each strip shall conform to the requirements of I.P and shall appear in the language of English/Hindi.
All labeling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in Drugs & Cosmetic Act 1940 and rules there under, following information should be available:
• A description of the syringe including the capacity/ A description of the Needle including the Gauge and the nominal length
• The word „Sterile‟</td><td></td><td></td></tr>
</table>

S.No.	Technical Specification (Amphotericin –B Injection)	Compliance Yes/No	Page in the bid submitted where documentary evidence is enclosed
	• That the syringe/needle is for single use only • A solvent incompatibility • The batch number • Name and address of the manufacturer • Date of Manufacture and Date of Expiry • Warning that the syringe is not to be used if the packaging is damaged or sterility protector is loose • CE marking • ISO symbol for “do not re-use”		
33)	**Labeling for secondary packaging:** **Secondary Package:** A label must be affixed either on the top and/or front surface of the secondary package. It should indicate: • A description of the syringe including the capacity and the type of nozzle/ A description of the needle including the gauze and the nominal length • Quantity of primary packages • The word „Sterile“ • That the syringe is for single use only • The batch number • The date (month and year) of sterilization • Name and address of the manufacturer • Date of Manufacture and Date of Expiry • Information for handling, storage and transportation		
34)	**Quality Assurance:** **Compliance:** The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per GMP included in Schedule M - III. and (f) the product should conform to ISO 13485.		
35)	**Evidence:** The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned. The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment. The Supplier shall provide a documentary evidence that the sterilization of the syringes has been carried out by validated sterilization procedures (with appropriate controls and recording devices) in case it has been carried out in their premises. If the facilities of other institution is used for sterilization, the approval of the licensing authority and documentary evidence for validated sterilization procedure should be made available. The supplier shall provide documentary evidence that the inks, glues and adhesives for the marking on the package and on the assembly of the syringe and		

S.No.	Technical Specification (Amphotericin –B Injection)	Compliance Yes/No	Page in the bid submitted where documentary evidence is enclosed
	its package (Wherever necessary) do not migrate across the walls. The supplier shall provide documentary evidence in regards to bio-compatibility of the device as per the requirements given in "Biological Evaluation of Medical Devices" IS 12572. The supplier shall provide a copy of CE certificate. The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment. The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.		
36)	**A. Packing:** **Primary Package:** Each syringe and needle shall be packed and sealed separately in a primary container. The material of each container should not have detrimental effects on the contents. The material and design should be such as to ensure: a) The maintenance of sterility under dry, clean and adequately ventilated storage conditions; b) The minimum risk of contamination of the contents during opening of the container and removal of the contents; c) Adequate protection of the contents during normal handling, transit and storage; d) That once opened, the container cannot be easily resealed, and it should be obvious that the container has been opened. e) Paper-PVC Blister: f) PVC Film: Transparent, clear, food grade, blister forming PVC film, film gauge- 200 microns, PE coating: 25 microns. g) Hard tempered Blister paper, VMCH coated, Thickness: 0.025mm.		
37)	**Secondary Package:** The primary package should be packed in boxes for easy handling, transport and distribution. The box may contain --- primary packages. It shall be fabricated from Millboard/ grey board/ cardboard with a minimum of bursting strength of 400gsm.		
38)	**B. Inspection:** The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier's factory and/or warehouse at a mutually agreeable time prior to the shipment of the product. Details of samples lifted for testing (such as Millboard/Greyboard boxes, batch no. etc;) should be pasted on the packing of 5 Ply Shipper and records to this effect to be made available to the purchaser		
39)	**C. Testing:** The Purchaser may cause independent laboratory testing to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser‟s		

S.No.	Technical Specification (Amphotericin –B Injection)	Compliance Yes/No	Page in the bid submitted where documentary evidence is enclosed
	choice if suitably equipped and qualified to conduct quality assurance tests on the product.		
40)	**D. Labelling on Shipper Package:** The external surface of insulated packages should be either white or in the natural color of corrugated carton. The labels on tertiary packaging must be attached to at least two sides. The label should include the name of the product, the number of secondary package (boxes) of Amphoterecin-B Injections and Disposable Syringes plus Disposable Needles, the name of the manufacturer, Master batch number, date of manufacture, and date of expiry. The label shall include bar code and be tear proof to be pasted on smooth surface to enable it to be read by bar code reader.		
41)	**E. Packing for Shipper Package:** The boxes shall be packed in weather resistant triple walled insulated corrugated 5-ply cartons, each ply having strength of minimum 150gsm. It should be fabricated from virgin quality „A" grade material. The overall dimension of the carton should be such that the product does not get damaged during transportation and storage. Each shipper package shall contain 50 secondary packs of Amphotericin-B for Injection, 50 seconday packs of Sterile water for injections and 50 secondary packs of Disposable syringe and Disposable Needle.		
42)	**F. Qualification of the Manufacturer:** The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to WHO-GMP standards. In case of medical devices the manufacturing facility must conform to the standards given in Schedule M-III of Drugs & Cosmetics Act and ISO 13485.		
43)	**G. Recalls:** If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.		
44)	**H. Colour Coding:** The labels on secondary packing, tertiary and shipper package shall be identified by WHITE background**.**		
45)	**I. Bar Coding:** Bar code shall be used to track down the product. It shall be printed on the label of Shipper containing 1) Product identification (GTIN 14) using application identifier (01) 2) Expiry Date in YYMMDD format & using application identifier (17)		

S.No.	Technical Specification (Amphotericin –B Injection)	Compliance Yes/No	Page in the bid submitted where documentary evidence is enclosed
	3) Master batch number using application identifier (10) Complete details on GS1 standards along with technical guidelines can be downloaded from www.gs 1india.org or www.gs1.org		
46)	**J. Markings:** All containers and invoices must bear the name of the product, expiry dates of and appropriate storage conditions. **Inner boxes:** The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser: • Generic name of the product • Strength in terms of active ingredient in mg per ml wherever required • Names and concentrations of the adjuvant/ preservative added wherever required • Manufacturer‟s name and registered address • Manufacturer‟s License number • Lot or batch number • Number of vials/ampoules/Syringes with needles contained in box • Date of manufacture (month and year) • Expiration date (month and year) • Instructions for storage and handling • Place of manufacture (Made in_____ _) **Exterior Shipping Cartons:** The following information shall be stenciled or labelled on theexteri or shipping cartons on all four sides in bold letters at least Ariel font size 14 with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser: • Generic name of the product • Strength in terms of active ingredient in mg per ml • Names and concentrations of the adjuvant/ preservative added • Lot or batch number • Date of manufacture (month and year) • Expiration date (month and year) • Manufacturer‟s name and registered address • Manufacturer‟s national registration number • Destination country license or registration number Consignee‟s address and emergency phone number including mobile number • Destination airport • Contract number • Number of ampoules/Syringes-needles pouches/boxes contained in the carton • Gross weight of each carton (in kg) • Carton containing ------- secondary packages • Instructions for storage and handling • Place of manufacture (Made in_____ _)		

S.No.	Technical Specification (Amphotericin –B Injection)	Compliance Yes/No	Page in the bid submitted where documentary evidence is enclosed
47)	**K. Documentation:** Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the product being supplied. Advance notice of arrival and advance shipping documentation: Copies of the documentation for the goods to be shipped must be sent at least seven days in advance of arrival of the shipment. In the case of an individual contract for a specific destination that requires a longer period of advance notice, a longer period should apply. The consignee(s) shall be intimated well in advance by registered letter/e-mail/ telephone, so that the products are collected from the airport immediately after arrival. The documentation must include the following: • Pre-advice defined by the Purchaser • Airway bill (AWB); • Supplier‟s invoice; • Packing list; • Lot release certificate (LRC) as per the requirements issued by the national regulatory authority (NRA) of the country of manufacture for each lot and • Any other document, certificate or instruction specified in the individual order. The documents shall be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignee, the Purchaser, and any other parties specified in the individual contract. **The pre-advice must contain the following information:** • Purchase order reference; • Consignee requisition reference; • Number of packages and gross weight (in kilograms). • Value of shipment (in Indian Rupees and US $); • AWB and flight number(s); • Date and time for place of departure, transit (if applicable), and arrival; • Instructions for collection; • Any other information specified in the individual contract must also be included for the consignee. The following information shall be stated on the airway bill: • Consignee‟s name, address, tel. number (including mobile no.) and e-mail ID. • Purchase order reference; • Consignee‟s requisition reference; • Instructions to: “Telephone consignee upon arrival (repeat telephone number);		
48)	**L. Dispatch:**		

Section IV Techncial Specifications

S.No.	Technical Specification (Amphotericin –B Injection)	Compliance Yes/No	Page in the bid submitted where documentary evidence is enclosed
	Shipments should be scheduled to arrive outside weekends and/or public holidays in the recipient country and airline bookings should be made well ahead of the date of departure.		

	*Our Minimum Requirements (***Artesunate Injection Kit)**	***Compliance Yes/No***	***Page in the bid submitted where documentary evidence is enclosed***
A.	***Specific requirements***		
	Artesunate Injection Kit consists of a vial of Artesunate Injection; an ampoule of 5% Sodium Bicarbonate Injection; an ampoule of Sodium Chloride Solution and Disposable Syringe along with Disposable needle. The individual items contained in the product shall be currently registered in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The individual items contained in the product shall also be currently registered in India and shall meet all the requirements of the licensing authority in India.		
1.	**Artesunate Injection:**		
a.	**Description:** Artesunate Injection contains a sterile powder containing Artesunate. Each vial shall contain - Artesunate IP 60 mg Artesunate Injection complies with WHO working document QAS/10.365/FINAL May 2011 (Adopted text for addition to The International Pharmacopoeia) The powder for injection and the reconstituted injection comply with the monograph for "Parenteral Preparations" included in the latest edition of International Pharmacopoeia. The injection is constituted by dissolving the contents of the sealed container in the requisite amount of Sterile Water for Injections, immediately before use. The quality of Artesunate injection should conform to the requirements of IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.		
b.	**Labelling:** The label on each vial shall conform to the requirements of I.P and shall appear in the language of English/Hindi. All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in IP, all labels shall state the quantity of Artesunate contained in the sealed container, the name of the manufacturer, manufacturing license number, address of manufacturer, lot number, and expiry date. The label shall conform to the requirements of Rule 96 of Drugs & Cosmetic Act.		
c.	**Packing:** **Primary Package:** 5 ml Vial (IP type 1 clear)(Containing Artesunate Powder for injection) closed with 20 mm Bromobutyl Rubber Plug and Sealed with flip off seal		

	*Our Minimum Requirements (***Artesunate Injection Kit)**	***Compliance Yes/No***	***Page in the bid submitted where documentary evidence is enclosed***
	and plastic overcap.		
2.	**Sodium Bicarbonate Injection:**		
a.	**Description:** A clear, colourless solution. Each ampoule shall contain 1 ml of Sodium Bicarbonate Injection (5%W/v). The quality of Sodium Bicarbonate and Sterile Water for Injection should conform to the requirements of IP. If not mentioned in IP then other Pharmacopoeia of equivalent accuracy in case of international transactions may be followed.		
b.	**Labelling:** The label on each ampoule shall conform to the requirements of I.P and shall appear in the language of English/Hindi. All abeling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in IP, all labels shall state the name of the manufacturer, manufacturing license number, address of manufacturer, lot number, and expiry date.		
c.	**Packing:** **Primary Package:** IP Type 1 clear plain glass ampoules. Each ampoule shall contain 1 ml of Sodium Bicarbonate injection (5%w/v). The ampoule should be sufficiently transparent to permit visual inspection of the contents.		
3.	**Sodium Chloride Injection:**		
a.	**Description:** A clear, colourless solution. Each ampoule shall contain 5 ml of Sodium Chloride Injection (0.9%W/v). The quality of Sodium Chloride and Sterile Water for Injection should conform to the requirements of IP. If not mentioned in IP then other Pharmacopoeia of equivalent accuracy in case of international transactions may be followed.		
b.	**Labelling:** The label on each ampoule shall conform to the requirements of I.P and shall appear in the language of English/Hindi. All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in IP, all labels shall state the name of the manufacturer, manufacturing license number, address of manufacturer, lot number, and expiry date.		

	*Our Minimum Requirements (***Artesunate Injection Kit)**	***Compliance Yes/No***	***Page in the bid submitted where documentary evidence is enclosed***
c.	**Packing:** **Primary Package:** IP Type 1 clear plain glass/FFS ampoule. Each ampoule shall contain 5 ml of Sodium Chloride injection (0.9%w/v). The ampoule should be sufficiently transparent to permit visual inspection of the contents.		
d.	**Secondary Package for Artesunate Injection + Sodium bicarbonate Injection + Sodium Chloride Injection:** One vial of Artesunate Injection, one ampoule of Sodium bicarbonate Injection and one ampoule of Sodium Chloride Injection are packed in PVC blisters sealed, thermo-formated trays having high rigidity and sufficient impact strength to provide break resistance packaging. The tray along with Instructions for reconstitution and administration of Artesunate Injection should be packed in a box for easy handling, transport and distribution. It shall be fabricated from Millboard/ grey board/ cardboard with a minimum of bursting strength of 300gsm.		
e.	**Labelling for secondary packaging:** A label must be affixed either on the top and/or front surface of the secondary package. It should indicate number of boxes of Artesunate injection + Sodium Bicarbonate Injection + Sodium Chloride Injection. Separately the name of the manufacturer, batch number, date of manufacture, date of expiry of Artesunate Injection, Sodium Bicarbonate Injection and Sodium Chloride Injection should be given. The master batch number of the Kit along with Date of Expiry should be given. The label should also give Storage requirements. The label shall conform to the requirements of Rule 96 of Drugs & Cosmetic Act.		
f.	**Quality Assurance:** **Compliance:** The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per WHO GMP requirements.		
g.	**Evidence:** The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned. The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment. The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment. The Supplier shall provide to the Purchaser a copy of the approval on		

<table>
<tr><th colspan="2">Our Minimum Requirements (Artesunate Injection Kit)</th><th>Compliance Yes/No</th><th>Page in the bid submitted where documentary evidence is enclosed</th></tr>
<tr><td></td><td>demand of each source material, constituent material and component for each lot intended for shipment.
The test data for raw materials including water for injection, glass container, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser‟s representatives when requested.
Details of samples lifted for testing (such as Millboard/Greyboard boxes, batch no. etc;) should be pasted on the packing of 5 Ply Shipper and records to this effect to be made available to the purchaser</td><td></td><td></td></tr>
<tr><td>4.</td><td>Disposable Syringe and Disposable Needle:</td><td></td><td></td></tr>
<tr><td>a.</td><td>Description (Disposable Syringe):

Disposable Syringes are Sterile Hypodermic Syringes for Single Use and are fabricated from virgin plastic. They shall conform to the standards given in IS 10258:2002. These are medical device intended for immediate use for administration of injectable preparations. They are supplied sterile and pyrogen – free and not to be re-sterilised or reused. The plastics and elastomer materials (polypropylene and polyethylene) of which the barrel and piston are made comply with the relevant specifications issued by BIS. The Syringes comply with the following standards regarding Dimensions including dead volume.

<table>
<tr><th>Capacity of the Syringe ml</th><th>Tolerance eq. or ex. to cap.</th><th>Tolerance < half of cap.</th><th>Max. Dead Vol. ml</th><th>Length of long Graduation Mark</th><th>Overall length of scale</th><th>Scale Interval ml</th><th>Increme. Betwee Graduatn lines m</th></tr>
<tr><td>05</td><td>+_4% of expelled vol</td><td>+_1.5 % nominal Cap, +1% of expelle</td><td>0.075</td><td></td><td>36</td><td>0.50</td><td>1</td></tr>
</table>

Polydimethylsiloxane (Silicone Oil) is applied to the internal walls of the barrel to assist in the smooth operation of the syringe but no excess be ensured capable of contaminating the contents at the time of use.</td><td></td><td></td></tr>
<tr><td>b.</td><td>Description (Disposable Needles):

Sterile Hypodermic Needles for Single Use comprise of a length of hypodermic grade stainless steel tube connected to a hub that is designed to mate with a syringe or an IV set. They shall conform to the standards given in IS 10654:2002. The other end of the tube is sharpened at the tip as per IS requirements. The tube is covered with a shield made from polypropylene. The hub fabricated from poly propylene is colour coded as per the requirements of ISO 6009. The union of the hub and needle tube is carried out with epoxy adhesive. This medical device in conjunction with Syringe is intended for immediate use for administration of injectable preparations. They are supplied sterile and pyrogen – free and not to be re-sterilised or reused.</td><td></td><td></td></tr>
</table>

<table>
<tr><th colspan="2">Our Minimum Requirements (Artesunate Injection Kit)</th><th>Compliance Yes/No</th><th>Page in the bid submitted where documentary evidence is enclosed</th></tr>
<tr><td></td><td>The Hypodermic needles shall comply with the following standards regarding Dimensions:
<table><tr><th>Needle Gauge</th><th>Colour of the hub</th><th>Nominal Length of the tube mm</th><th>Tolerance In length mm</th><th>Nominal outside diameter Of needle mm</th><th>Diameter of stylet for normal walled</th></tr><tr><td>23</td><td>Blue</td><td>25</td><td>+ 1, -2</td><td>0.6</td><td>0.25</td></tr></table></td><td></td><td></td></tr>
<tr><td>c.</td><td>Labelling:

The label on each strip shall conform to the requirements of I.P and shall appear in the language of English/Hindi.

All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in Drugs & Cosmetic Act 1940 and rules there under, following information should be available:

A description of the syringe including the capacity/ A description of the Needle including the Gauge and the nominal length
The word „Sterile“
That the syringe/needle is for single use only
A solvent incompatibility
The batch number
Name and address of the manufacturer
Date of Manufacture and Date of Expiry
Warning that the syringe is not to be used if the packaging is damaged or sterility protector is loose
CE marking
ISO symbol for “do not re-use”</td><td></td><td></td></tr>
<tr><td>d.</td><td>Labelling for secondary packaging:

Secondary Package:

A label must be affixed either on the top and/or front surface of the secondary package. It should indicate:
A description of the syringe including the capacity and the type of nozzle/A description of the needle including the gauze and the nominal length
Quantity of primary packages
The word „Sterile“
That the syringe is for single use only
The batch number
The date (month and year) of sterilization
Name and address of the manufacturer</td><td></td><td></td></tr>
</table>

	*Our Minimum Requirements (***Artesunate Injection Kit)**	***Compliance Yes/No***	***Page in the bid submitted where documentary evidence is enclosed***
	Date of Manufacture and Date of Expiry Information for handling, storage and transportation		
e.	**Quality Assurance:** **Compliance:** The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per cGMP included in Schedule M - III. (f) the product is WHO pre-qualified and (g) the product should conform to ISO 13485.		
f.	**Evidence:** The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned. The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment. The Supplier shall provide a documentary evidence that the sterilization of the syringes has been carried out by validated sterilization procedures (with appropriate controls and recording devices) in case it has been carried out in their premises. If the facility of other institution is used for sterilization, the approval of the licensing authority and documentary evidence for validated sterilization procedure should be made available. The supplier shall provide documentary evidence that the inks, glues and adhesives for the marking on the package and on the assembly of the syringe and its package (Wherever necessary) do not migrate across the walls. The supplier shall provide documentary evidence in regards to bio-comapatibility of the device as per the requirements given in “Biological Evaluation of Medical Devices” IS 12572. The supplier shall provide a certificate of analysis of Polydimethylsiloxane (used for lubrication) conforming to the requirements of IP. The supplier shall provide a copy of CE certificate. The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment		
g.	**Packing:** **Primary Package:**		

	*Our Minimum Requirements (***Artesunate Injection Kit)**	***Compliance Yes/No***	***Page in the bid submitted where documentary evidence is enclosed***
	Each syringe and needle shall be packed and sealed separately in a primary container. The material of each container should not have detrimental effects on the contents. The material and design should be such as to ensure: a) The maintenance of sterility under dry, clean and adequately ventilated storage conditions; b) The minimum risk of contamination of the contents during opening of the container and removal of the contents; c) Adequate protection of the contents during normal handling, transit and storage; d) That once opened, the container cannot be easily resealed, and it should be obvious that the container has been opened. Paper-PVC Blister:. -PVC Film: Transparent, clear, food grade, blister forming PVC film, film gauge- 200microns, PE coating: 25 microns. -Hard tempered Blister paper, VMCH coated, Thickness: 0.025mm		
h.	**Secondary Package:** The primary package should be packed in boxes for easy handling, transport and distribution. The box may contain --- primary packages. It shall be fabricated from Millboard/ grey board/ cardboard with a minimum of bursting strength of 400gsm.		
B.	***Inspection:***		
	The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier‟s factory and/or warehouse at a mutually agreeable time prior to the shipment of the product.		
C.	***Testing:***		
	The Purchaser may cause independent laboratory testing to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser's choice if suitably equipped and qualified to conduct quality assurance tests on the product.		
D.	***Labelling on Shipper Package:***		
	The external surface of insulated packages should be either white or in the natural color of corrugated carton. The labels on tertiary packaging must be attached to at least two sides. The label should include the name of the product, the number of secondary package (boxes) of Artesunate Injection + Sodium Bicarbonate Injection + Sodium Chloride Injection and Disposable Syringes plus Disposable Needles, the name of the manufacturer, Mater batch number and date of expiry.		

	*Our Minimum Requirements (***Artesunate Injection Kit)**	***Compliance Yes/No***	***Page in the bid submitted where documentary evidence is enclosed***
	The label shall include bar code and be tear proof to be pasted on smooth surface to enable it to be read by bar code reader.		
E.	***Packing for Shipper Package:***		
	The secondary packages of Artesunate Injection + Sodium Bicarbonate Injection + Sodium Chloride Injection and that of Syringes + needles shall be packed in weather resistant triple walled insulated corrugated 5-ply cartons, each ply having strength of minimum 150gsm. It should be fabricated from virgin quality „A" grade material. Burst factor of individual ply should be not less than 22. GSM of the shipper should be not less than 13 Kg/cm2 . Overall dimensions of the carton should be such that the product does not get damaged during transportation and storage.		
F.	***Shelf Life of Artesunate Injection Kit:***		
	36 months, At least 5/6th of the shelf life must remain at the time of shipment. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the offered package The expiry date of the Artesunate Injection Kit shall be the same as that of Artesunate Injection being the constituent of product with the shortest shelf life.		
G.	***Numbering of shipper packaging:***		
	All boxes should be numbered consecutively. Shipping documents should be included in the box labelled number 1 (consignee wise),		
H.	***Qualification of the Manufacturer:***		
	The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to WHO-GMP standards. In case of medical devices the manufacturing facility must conform to the standards given in ISO 13485 and Schedule M-III of Drugs & Cosmetic Act.		
I.	***Recalls:***		
	If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.		
J.	***Model Inserts:***		
	An insert containing information in regards to adverse drug reactions and precautions (to be observed while taking the drug) of all the drugs included in the product should form part of each secondary pack.		
K.	***Colour Coding:***		

	*Our Minimum Requirements (***Artesunate Injection Kit)**	***Compliance Yes/No***	***Page in the bid submitted where documentary evidence is enclosed***
	The labels on secondary packing, and shipper package shall be identified by WHITE background.		
L.	***Bar Coding:***		
	Bar code shall be used to track down the product. It shall be printed on the label of Shipper containing 1) Product identification(GTIN 14) using application identifier (01) 2) Expiry Date in YYMMDD format & using application identifier (17) 3) Master batch number using application identifier (10) Complete details on GS1 standards along with technical guidelines can be downloaded from www.gs 1india.org or www.gs1.org		
M	***Documentation***		
	Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the product being supplied.		
a.	**Advance notice of arrival and advance shipping documentation:**		
	Copies of the documentation for the goods to be shipped must be sent at least seven days in advance of arrival of the shipment. In the case of an individual contract for a specific destination that requires a longer period of advance notice, a longer period should apply. The consignee(s) shall be intimated well in advance by registered letter/e-mail/ telephone, so that the products are collected from the airport immediately after arrival. The documentation must include the following: Pre-advice defined by the Purchaser Airway bill (AWB); Supplier‟s invoice; Packing list; Lot release certificate (LRC) as per the requirements issued by the national regulatory authority (NRA) of the country of manufacture for each lot and Any other document, certificate or instruction specified in the individual order.		
	The documents shall be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignee, the Purchaser, and any other parties specified in the individual contract. The pre-advice must contain the following information: Purchase order reference; Consignee requisition reference; Number of packages and gross weight (in kilograms). Value of shipment (in Indian Rupees and US $); AWB and flight number(s); Date and time for place of departure, transit (if applicable), and arrival; Instructions for collection; Any other information specified in the individual contract		

	*Our Minimum Requirements (***Artesunate Injection Kit)**	***Compliance Yes/No***	***Page in the bid submitted where documentary evidence is enclosed***
	must also be included for the consignee. The following information shall be stated on the airway bill: Consignee's name, address, telephone number (including mobile no.) and e-mail ID. Purchase order reference; Consignee's requisition reference; • Instructions to: "Telephone consignee upon arrival *(repeat telephone number);*		
N.	***Dispatch:***		
	Shipments should be scheduled to arrive outside weekends and/or public holidays in the country and airline bookings should be made well ahead of the date of departure.		

Section IV Techncial Specifications

S.No.	Technical Specification (Paromomycin IM Injection for Kala-Azar)	Compliance Yes/No	Page in the bid submitted where documentary evidence is enclosed
1)	**Description of Store: P**arammomycin IM injection 1*2 ml ampoules containing 375 mg of Paromomycin per ml.		
2)	**Shelf Life:** Minimum 2years whne stored below 30 C and protected from light.		
3)	**Special precautions for storage:** Store below 30 C. Protect form lisght. Do not freeze. DO NOT STORE partially used ampoules for futre patient use.		
4)	**Nature and Content of Container**: 2 ml Type 1 amber glass ampoules, supplied in packs of 10 ampoules.		
5)	**Instructions fo Use and Handling and Disposal:** For single use only. Any unsused paromomycin from opened ampoules should be discarded.		
6)	**Labelling /Printing:**		
A	• **On the injection of Ampoule** • Name of injection product • Name of manufacture with address • IM use only • License No. • Lot No. and Batch No. • Manufacturing and expiry date • The contents of injection per ml • Govt. Of India Supply Not for Sale (Preferably in red colour, or in any contrast colour)		
(b)	• **On the Primary Packing of sliding Cardbox box** • Name of injection product • Name of manufacture with address • IM use only • License No. • Lot No. and Batch No. • Manufacturing and expiry date • The contents of injection per ml • Govt. Of India Supply Not for Sale (Preferably in red colour, or in any contrast colour) • Dosage-Adult/Children • Indications for use		

S.No.	Technical Specification (Paromomycin IM Injection for Kala-Azar)	Compliance Yes/No	Page in the bid submitted where documentary evidence is enclosed
	• Adverse effect/Side effects • Precautions • Storage Condition		
(C)	**On the Secondary Packing/Inner Carton and Outer shipper of Corrugated Box** • Name of injection product • Name of manufacture with address • IM use only • License No. • Lot No. and Batch No. • Manufacturing and expiry date • The contents of the container • Govt. Of India Supply Not for Sale (Preferably in red colour, or in any contrast colour) • Precaution for transportation • Storage condition • The box should be packed with thermocol material to prevent breakage.		
7)	**Good Manufacturing Practices (GMP):** The manufacturing facility must confirm to GMP as per Schedule 'M' of the Drugs & Cosmetic Act.		
8)	Product should be COPP complying		

PART B: GENERAL TECHNICAL SPECIFICATIONS

PART B: GENERAL TECHNICAL SPECIFICATIONS

Bidders are requested to complete the "Your Offer" column by Yes or No. Yes indicates compliance with the specification, whereas No indicates deviation. In case of deviation, please indicate the nature and extent of the deviation in the "Deviation" column.

General Specifications

Our Minimum Requirements		*Please fill in*	Deviation
1	**Product and Package Specifications**		
1.1	The pharmaceuticals to be purchased by the Purchaser under this Invitation for Bids are included in the Purchaser's national essential drugs list or national formulary. The required packing standards and labeling should meet the Good Manufacturing Practice (GMP) standards in all respects	Yes/No	
1.2	Product specifications indicate dosage form (e.g. capsule, tablet, injectable, emulsion, suspension etc) and the drug content (exact number of mg. or percentage v/v with acceptable range). The products should conform to standards specified in Indian Pharmacopoeia. In case the pharmaceutical is not included in the specified compendium, the Supplier, upon award of the contract, must provide the reference standards and validated testing protocols (as per ICH Guidelines) to allow for quality control testing.	Yes/No	
1.3	Not only the pharmaceuticals items, but also the packaging components (e.g. vials, disposables syringes and disposable needles etc.) should also conform to specifications suitable for use in a climate similar to that prevailing in the country of the Purchaser. The products supplied should have been subjected to long-term stability conditions at 30°C and 65% r.h (relative humidity).	Yes/No	
1.4	All packaging must be properly sealed and tamper-evident	Yes/No	
1.5	Pharmaceuticals requiring refrigeration for stability must specifically indicate storage requirements on labels and containers and be shipped in the special containers to ensure stability in transit from point of shipment to the port of entry	Yes/No	
2	**Product information**		
2.1	The following information will be required for each pharmaceutical product offered by the Bidder: i) International Non-proprietary Name (INN); ii) Brand name (if it appears on label); iii) Name and address of the manufacturer; iv) Country of Origin; and v) Compendia standards.	Yes/No	
2.2	Upon award, the supplier shall on demand provide a translated version in English, of the prescriber's information for any specific product, the Purchaser may request		
2.3	Failure to include any of this information, at the discretion of the Purchaser, render the Bid non-responsive	Yes/No	

3	**Expiration Date**		
3.1	All products must indicate the dates of manufacture and expiry. In addition, unless otherwise stated in Part A of these Specifications, all products must arrive at the port of entry (for imported pharmaceuticals) or consignees' warehouse (for local purchases) with a remaining shelf life of at least five-sixths (5/6ths) of the total stipulated shelf life at the time of manufacture	Yes/No	
3.2	Shelf life of various – As in Part A	Yes/No	
4	**Recalls**		
4.1	If products must be recalled because of problems with product quality as a result of quality check carried out during the life span of the drug or adverse reactions to the pharmaceutical, the Supplier will be obligated to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable pharmaceuticals, or withdraw and give a full refund if the product has been taken off the market due to safety problems.	Yes/No	
5	**Labeling Instructions**		
5.1	The label for each pharmaceutical products shall meet the WHO GMP standards and include: i) the INN or generic name prominently displayed and above the brand name, where a brand name has been given. Brand names should not be bolder or larger than the generic name; ii) the active ingredient per unit dose, injection, sterile water etc.; iii) the applicable pharmacopoeia standard; iv) content per pack v) special storage requirements; vi) batch number; and vii) date of manufacture and date of expiry	 Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No	
5.2	The outer case or carton should also display the above information	Yes/No	

6	All cases should prominently indicate the following: i) the generic name of the product; ii) date of manufacture and expiry; iii) batch number; and iv) quantity per case. No case should contain pharmaceutical products from more than one batch.	 Yes/No Yes/No Yes/No Yes/No	
7	**Qualifications of manufacturer:**		
	The Bidder shall furnish a certificate from the competent Drug Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to WHO GMP Standards	Yes/No	
8	**Standards and Quality Assurance Requirements**		
8.1	All products must meet		
a	Conform to all the specifications contained herein; and	Yes/No	
b	must undergo strict raw material inspection, in process checks, appropriate material handling to eliminate cross contamination (of molecules) and final product testing to ensure quality and consistency of the products	Yes/No	
8.2	The successful Bidder will be required to furnish to the purchaser a) with each consignment, a certificate of quality assurance test results (of Pharmaceutical & packing materials) in conformity with the concerning quantitative assay, chemical analysis, sterility, Bacterial Endotoxin Test, content uniformity, microbial limit of oral dosage forms as well and other tests as applicable to the product being supplied and Part A of these Specifications; b) assay methodology of all tests, if requested; c) evidence of bio-availability and/or bio-equivalence for all pharmaceuticals. d) evidence of basis for expiration dating and other stability data on the offered package (as per climatic conditions prevalent in India) concerning the commercial final package upon request. e) Package integrity test results	 Yes/No Yes/No Yes/No Yes/No	

8.3	The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms	Yes/No	
8.4	SPECIFICATION OF PACKAGING MATERIAL		
8.4.1	General Specifications		
	(i) The goods are TROPICIALIZED with moisture barrier properties for drug stability under field condition. (ii) Quality Assurance is according to Norm ISO 9001/EN 2901 for alu-foil and any other packing material. (iii) Complete with self-adhesive patient labels. (iv) Perforation and folding lines, to allow packet use	Yes/No Yes/No Yes/No Yes/No Yes/No	

THE PRODUCTS OFFERED ARE IN ACCORDANCE WITH THE SPECIFICATIONS AND REQUIREMENTS

YES / NO

ANY DEVIATION MUST BE LISTED BELOW

_____

_____

PART C

(I) Inspection & Tests (Clause 9 of GCC)

	Our Minimum Requirements	***Please fill in***
	The following inspection procedures and tests are required by the Purchaser	
a	Three sets of samples of required quantity of each item will be drawn at random from each batch by the Purchaser's Inspector at the manufacturer's premises & sealed before dispatch	Yes/No
b	One set of sealed sample will be sent to an independent laboratory selected by the Inspector for conducting the required test to confirm whether the samples conform to the prescribed specification. One set of sealed sample will be retained with the manufacturer as counter sample and another set will be retained by the inspector	Yes/No
c	The sample retained with the manufacturer & Inspector will not be dispatched to the destination along with the supplies after the samples are certified to be in conformity with prescribed specification by the testing laboratory.	Yes/No
d	Dispatch clearance will be issued by the purchaser on the basis of test report, accepting or rejecting the batch as the case may be	Yes/No
e	The Goods will be dispatched only after the above inspection and test procedure has been followed and dispatch clearance issued to accept the consignment	Yes/No
f	The Purchaser/consignee shall have the right to draw samples at random from the consignment anytime during the shelf life of the Goods and get them retested to satisfy whether the lots conform to the laid down specifications. In the event of the product failing to conform to specifications, the consignee shall reject that batch of supply and inform the supplier for arranging replacement of the rejected batches at supplier's cost.	Yes/No

(II) SPECIAL INSTRUCTIONS	
Each good, inner carton and nested cartons to have the following words printed DIAGONALLY ACROSS THE LABLE with bold letters. "NVBDCP CENTRAL GOVERNEMENT SUPPLY "	***Yes/No***
Life of the product, indicating the date of manufacture and date of expiry should be printed as per Drugs & Cosmetics Act-India	
Equivalency of Standards & Codes Wherever reference is made in the Technical Specifications to specific standards and codes to be met by the Product to be furnished or tested, the provisions of the latest current edition or revision of the relevant standards or codes in effect shall apply, unless otherwise expressly stated in the Contract. Where such standards and codes are national or authoritative standards that ensure substantial equivalence to the standards and codes specified will be acceptable	***Yes/No***
Packing (Clause 10 of GCC) Add as clause 10.3 of the GCC the following – Packing Instruction: The supplier will have to make unit packing for each combi blister pack which will be marked on three sides with proper paint/indelible ink, the following in addition to what is mentioned in PART A; i) Project : ii) RITES Purchase Order No. : iii) Country of origin of Goods : iv) Supplier's Name and : v) Packing list reference number : Each outer packing containing the unit packing should have the following label printed in bold letters in large size. i) Purchaser's Name: Govt. of India, through RITES. ii) Project: \ iii) RITES Purchase Order No : iv) Country of origin of Goods: v) Supplier's Name	***Yes/No***
Any other labeling requirement which the purchaser may ask at the time of approving the labeling samples	***Yes/No***

Bar Coding Requirements

Section A) Primary packaging (Item level and monocarton level)

At individual item level (strip of 10 tablets, syrup bottle, injections, vials etc) and/ or on its monocarton (wherever applicable), are required to have a pre printed barcode on its product packaging using either of the barcode symbologies mentioned below:

a) GS1 linear barcode symbology (EAN-13/UPC-A/EAN-8) to encode GTIN (Global Trade Identification Number) within the barcode.

or

b) GSI Data Matrix symbology to encode 14 digits product code (GTIN14) within the barcode and using (01) application identifier (to be used where printing space is extremely limited).

Examples of the same are reproduced at Annexure 'A'.

All other human readable information on product packaging shall be as required under existing Regulatory labeling & marking requirements.

Section B) Secondary level Packaging (Intermediate packaging)
At secondary level packaging (e.g. box of 10 strips containing 10 tabs each, pack of 10 vials, pack of 10 injections etc), barcode encoding following information to be stickered or preprinted on secondary packaging:

1) Product identification Code (GTIN-14 of secondary pack) using application identifier (01).
2) Expiry date in **YYMMDD** format using application identifier (17)
3) Batch/Lot Number using application identifier (10)

GSI-128 barcode symbology to be used to generate the barcode.

Examples of the same are reproduced at Annexure 'B'.

All other human readable information on product packaging shall be as required under existing Regulatory labeling & marking requirements.

Section C) Tertiary level packaging (Shipper level packaging)

At shipper level packaging, a single label containing two barcodes needs to be generated and stickered. The barcodes will encode following information:

1) Product Identification Code (GTIN-14 of shipper level pack) using application identifier (01).
2) Expiry Date in **YYMMDD** format using application identifier (17)
3) Batch/Lot Number using application identifier (10)

The second barcode will contain the following information:

1) SSCC (Serial Shipping Container Code) using application identifier (00)

Examples of the same are reproduced at Annexure 'C'.

All other human readable information on product packaging shall be as required under existing Regulatory labeling & marking requirements.

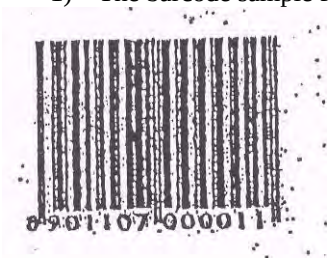
Annexure "A"

Examples of Primary Level Packaging

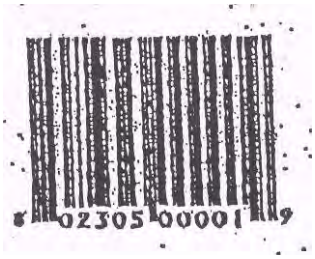
For generation of GSI barcode at primary level packaging either of the mentioned symbologies can be used, following GSI General Specifications.

The following GSI barcode symbologies are available as options:-

1) The barcode sample for EAN-13 barcode symbology encoding GTIN-13



2) The barcode sample for UPC-A barcode symbology encoding GTIN-12



Note: Both GTIN-13 GTIN-12 are in extensive use worldwide

3) The barcode sample for EAN-8 barcode symbology encoding GTIN-8 (Used where printing space is a constraint)

4) The barcode sample for GSI Data Matrix barcode symbology encoding GTIN-14 (Used where printing space is extremely limited)

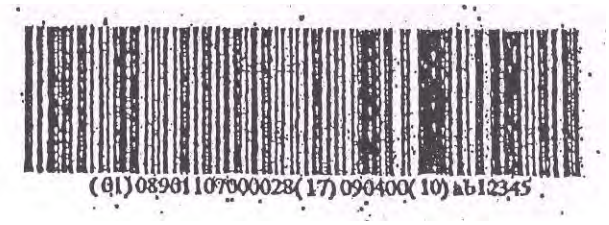
(01)08901107000011

Annexure "B"

Example of Secondary level Packaging

The barcode will encode :

1) Product identification (GTIN 14 of secondary pack) using application identifier (01)
2) Expiry date in **YYMMDD** format using application identifier (17)
3) Batch/Lot Number using application identifier (10)



Annexure "C"

Example of Tertiary level packaging (Shipper level packaging)

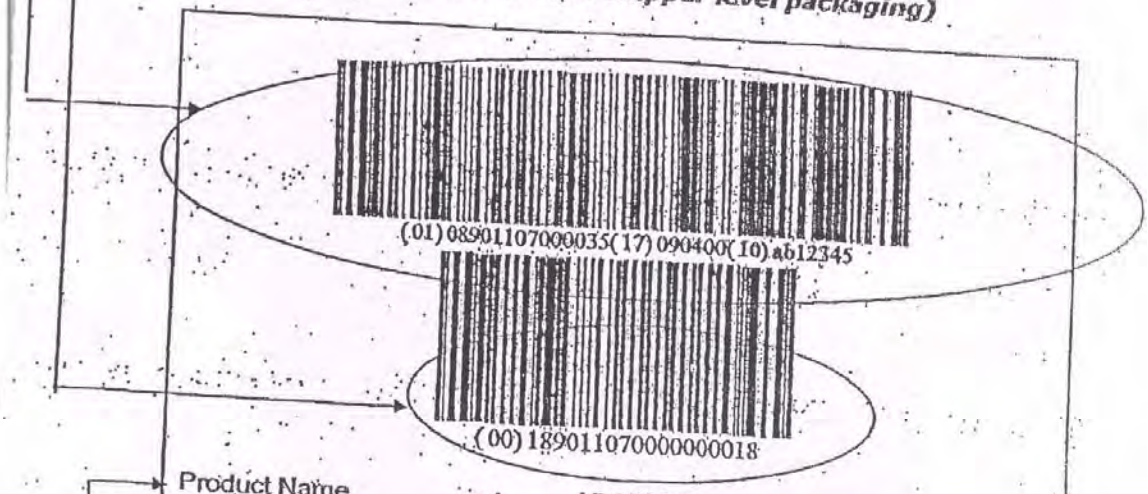
The first barcode will encode the following:

1) Product Identification (GTIN 14 of Shipper Pack) using application identifier (01)
2) Expiry Date in YYMMDD format using application identifier (17)
3) Batch/Lot Number using application identifier (10)

The second barcode will encode the following:

SSCC (Serial Shipping Container Code)

(Single Label for each Shipper level packaging)



Product Name	:	ABCDXYZ
Expiry Date	:	04/09 (April/09)
Batch No.	:	ab12345
Shipper carton Serial No.	:	189011070000000018

Human Readable Information

Complete details on GS1 standards along with technical guidelines are available at www.gs1india.org under "downloads" section.

SECTION V

SAMPLE FORMS

SAMPLE FORMS

1. Bid Form

Date: *[insert: **date of bid**]*

Loan/Credit No.: *[Purchaser insert: **number**]*

[Purchaser specify: "IFB No.: [number]"]

*[Insert: **name of Contract**]*

To: *[Purchaser insert: **Name and address of Purchaser**]*

Dear Sir or Madam:

Having examined the Bidding Documents, including Addenda Nos. *[insert **numbers**]*, the receipt of which is hereby acknowledged, we, the undersigned, offer to supply and deliver the Goods under the above-named Contract in full conformity with the said Bidding Documents for the sum of:

	*[insert: **amount of local currency in words**]*	*([insert: **amount of local currency in figures**])*
plus	*[insert: **amount of foreign currency A in words**]*	*([insert: **amount of foreign currency A in figures**])*
[as appropriate, include the following]		
plus	*[insert: **amount of foreign currency B in words**]*	*([insert: **amount of foreign currency B in figures**])*
plus	*[insert: **amount of foreign currency C in words**]*	*([insert: **amount of foreign currency C in figures**])*

(hereinafter called "the Total Bid Price") or such other sums as may be determined in accordance with the terms and conditions of the Contract. The above amounts are in accordance with the Price Schedules attached herewith and are made part of this bid.

We undertake, if our bid is accepted, to deliver the Goods in accordance with the delivery schedule specified in the Schedule of Requirements.

If our bid is accepted, we undertake to provide a performance security in the form, in the amounts, and within the times specified in the Bidding Documents.

We agree to abide by this bid, for the Bid Validity Period specified in Clause 17.1 of the Bid Data Sheet and it shall remain binding upon us and may be accepted by you at any time before the expiration of that period.

Until the formal final Contract is prepared and executed between us, this bid, together with your written acceptance of the bid and your notification of award, shall constitute a binding Contract between us. We understand that you are not bound to accept the lowest or any bid you may receive.

We undertake that, in competing for (and, if the award is made to us, in executing) the above contract, we will strictly observe the laws against fraud and corruption in force in India namely "Prevention of Corruption Act 1988".

We hereby certify that we have taken steps to ensure that no person acting for us or on our behalf will engage in bribery. Commissions or gratuities, if any, paid or to be paid by us to agents relating to this bid, and to contract execution if we are awarded the Contract, are listed below:

Name and Address of Agent	Amount and Currency	Purpose of Commission or Gratuity

(if none, state "none")

Dated this *[insert: **number**]* day of *[insert: **month**]*, *[insert: **year**]*.

Signed: _____

Date: _____

In the capacity of *[insert: **title or position**]*

Duly authorized to sign this bid for and on behalf of *[insert: **name of Bidder**]*

2a. Price Schedule for indigenous items & already imported goods

Schedule No :-_____

Name of Bidder _____. IFB Number _____. Page _____ of ____.

1	2	3	4	5						6	7	8	9
Schedule No	Product	Unit	Quantity offered	**Price for each unit**						Total Unit price	Total price	Name of manufacturer	Country of origin
				Ex-factory Ex-warehouse Ex-showroom Off-the-shelf	Excise duty, if any		Sales Tax/ VAT if any		Other charges including inland transportation, incidental charges etc.				
					In %	In INR	In %	In INR					
				(a)		(b)		(c)	(d)	(a+b+c+d)	4 x 6		

Note:

(a) In case of discrepancy between unit price and total price, the unit price shall prevail.

(b) In case of discrepancy between price quoted in figure and words, price in words, shall prevail.

(c) "We hereby declare that in quoting the above price, we have taken into account the entire credit on inputs available under the CENVAT CREDIT scheme & VAT.

(d) Prices should be quoted for each schedules separately

(e) Seperate sheet for each schedule is to be provided

Total Bid Price:
Currency:
In figures:
In words:

Signed: _____

Dated: _____

In the capacity of: *[insert:* ***title or other appropriate designation*** *]*

2b. Price Schedule for imported items

Schedule No :-_____

Name of Bidder _____. IFB Number _____. Page _____ of ____.

1	2	3	4	5			6	7	8	9	10
Schedule No	Product	Unit	Quantity offered	**Price for each unit**			Total Unit price per Schedule	Total price per Schedule(4+6)	Local agent's commission	Name of manufacturer	Country of origin
				CIF (Indian port)	Custom duty	Other charges including inland transportation etc.					
				(a)	(b)	(c)	(a+b+c)	4 x 6			

Note:

a) In case of discrepancy between unit price and total price, the unit price shall prevail.

b) In case of discrepancy between price quoted in figure and words, price in words, shall prevail.

c) Prices should be quoted for each schedules separately.

d) Seperate sheet for each schedule is to be provided

e) Local agent's commission shall be filled in INR

Total Bid Price:
Currency:
In figures:
In words:

Signed: _____

Dated: _____

In the capacity of: *[insert: **title or other appropriate designation**]*

3. Bid Security Form

Date: *[insert: **date**]*
IFB: *[insert: **name and number of IFB**]*
Contract: *[insert: **name and number of Contract**]*

To: *[insert: **name and address of Purchaser**]*

WHEREAS *[insert: **name of Bidder**]* (hereinafter called "the Bidder") has submitted its bid dated *[insert: **date of bid**]* for the performance of the above-named Contract (hereinafter called "the Bid")

KNOW ALL PERSONS by these present that WE *[insert: **name of bank**]* of *[insert: **address of bank**]* (hereinafter called "the Bank") are bound unto *[insert: **name of Purchaser**]* (hereinafter called "the Purchaser") in the sum of: *[insert: **amount**]*, for which payment well and truly to be made to the said Purchaser, the Bank binds itself, its successors and assigns by these presents.

Sealed with the Common Seal of the said Bank this *[insert: **number**]* day of *[insert: **month**]*, *[insert: **year**]*.

THE CONDITIONS of this obligation are the following:

1. If, after the bid submission deadline, the Bidder

   (a) withdraws its bid during the period of bid validity specified by the Bidder in the Bid Form, or

   (b) does not accept the Purchaser's corrections of arithmetic errors in accordance with the Instructions to Bidders; or

2. If the Bidder, having been notified of the acceptance of its bid by the Purchaser during the period of bid validity

   (a) fails or refuses to sign the Contract Agreement when required; or

   (b) fails or refuses to issue the performance security in accordance with the Instructions to Bidders.

   (c) In case of any false, incorrect or misleading information provided in the bid.

We undertake to pay to the Purchaser up to the above amount upon receipt of its first written demand, without the Purchaser having to substantiate its demand, provided that in its demand the Purchaser will note that the amount claimed by it is due to it, owing to the occurrence of any one of the two above-named CONDITIONS, and specifying the occurred condition or conditions.

This guarantee will remain in full force up to and including *[insert: **the date that is 45 days after the period of bid validity**]*, and any demand in respect thereof must reach the Bank not later than the above date.

For and on behalf of the Bank

Signed:_____
Date: _____

in the capacity of: *[insert: **title or other appropriate designation**]*

Common Seal of the Bank

4. Form of Contract Agreement

THIS CONTRACT AGREEMENT is made

the *[insert: **number**]* day of *[insert: **month**]*, *[insert: **year**]*.

BETWEEN

(1) *[insert: **Name of Purchaser**]*, a *[insert: **description of type of legal entity,** for example, an agency of the Ministry of .... of the Government of [insert: **country of Purchaser**], or corporation incorporated under the laws of [insert: **country of Purchaser**]]* and having its principal place of business at *[insert: **address of Purchaser**]* (hereinafter called "the Purchaser"), and

(2) *[insert: **name of Supplier**]*, a corporation incorporated under the laws of *[insert: **country of Supplier**]* and having its principal place of business at *[insert: **address of Supplier**]* (hereinafter called "the Supplier").

WHEREAS the Purchaser invited bids for certain goods and ancillary services, viz., *[insert: **brief description of goods and services**]* and has accepted a bid by the Supplier for the supply of those goods and services at a unit rate of *[insert: **contract price in words and figures**]* (hereinafter called "the Contract Price") during the period of contract i.e. _____

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.

2. The following documents shall constitute the Contract between the Purchaser and the Supplier, and each shall be read and construed as an integral part of the Contract:

   (a) This Contract Agreement

   (b) Instruction to bidder

   (c) General Conditions of Contract

   (d) Technical Requirements (including Technical Specifications, Functional Requirements and Implementation Schedule)

   (e) The Supplier's bid and original Price Schedules

   (f) The Schedule of Requirements

   (g) The Purchaser's Notification of Award

   (h) *[Add here: **any other documents**]*

3. In consideration of the payments to be made by the Purchaser to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Purchaser to provide the Goods and Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.

4. The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the Goods and Services and the remedying of defects therein, the Contract Price or such

other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

Brief particulars of the goods and services which shall be supplied/provided by the Supplier are as under:

SL. NO.	BRIEF DESCRIPTION OF PHARMACEUTICALS & VACCINES	UNIT PRICE	TOTAL PRICE	DELIVERY TERMS

TOTAL VALUE:

Delivery Schedule:

For and on behalf of the Purchaser

Signed: _____

in the capacity of *[insert: **title or other appropriate designation**]*

in the presence of _____

For and on behalf of the Supplier

Signed: _____

in the capacity of *[insert: **title or other appropriate designation**]*

in the presence of _____

CONTRACT AGREEMENT

dated the *[insert: **number**]* day of *[insert: **month**]*, *[insert: **year**]*

BETWEEN

*[insert: **name of Purchaser**]*, "the Purchaser"

and

*[insert: **name of Supplier**]*, "the Supplier"

5.a Performance Security Bank Guarantee

(unconditional)

Date: *[insert: **date**]*
IFB: *[insert: **name or number of IFB**]*
Contract: *[insert: **name or number of Contract**]*

To: *[insert: **name and address of Purchaser**]*

Dear Sir or Madam:

We refer to the Contract Agreement ("the Contract") signed on *[insert: **date**]* between you and *[insert: **name of Supplier**]* ("the Supplier") concerning the supply and delivery of *[insert: **a brief description of the Goods**]*. By this letter we, the undersigned, *[insert: **name of bank**]*, a bank (or company) organized under the laws of *[insert: **country of bank**]* and having its registered/principal office at *[insert: **address of bank**]*, (hereinafter, "the Bank") do hereby jointly and severally with the Supplier irrevocably guarantee payment owed to you by the Supplier, pursuant to the Contract, up to the sum of *[insert: **amount in numbers and words**]*. This guarantee shall be reduced or expire as provided for by GCC Sub-Clause 8.4.

We undertake to make payment under this Letter of Guarantee upon receipt by us of your first written demand signed by your duly authorized officer declaring the Supplier to be in default under the Contract and without cavil or argument any sum or sums within the above-named limits, without your need to prove or show grounds or reasons for your demand and without the right of the Supplier to dispute or question such demand. Our liability under this Letter of Guarantee shall be to pay to you whichever is the lesser of the sum so requested or the amount then guaranteed under this Letter in respect of any demand duly made under this Letter prior to expiry of this Letter of Guarantee, without being entitled to inquire whether or not this payment is lawfully demanded.

This Letter of Guarantee shall be valid from the date of issue until the date of expiration of the guarantee, as governed by the Contract. Except for the documents herein specified, no other documents or other action shall be required, notwithstanding any applicable law or regulation. Our liability under this Letter of Guarantee shall become null and void immediately upon its expiry, whether it is returned or not, and no claim may be made under this Letter after such expiry or after the aggregate of the sums paid by us to you shall equal the sums guaranteed under this Letter, whichever is the earlier. All notices to be given under this Letter shall be given by registered (airmail) post to the addressee at the address herein set out or as otherwise advised by and between the parties hereto.

This guarantee shall expire no later than the ____ day of _____, 2_____, and any demand for payment under it must be received by us at this office on or before that date.

We hereby agree that any part of the Contract may be amended, renewed, extended, modified, compromised, released, or discharged by mutual agreement between you and the Supplier, and this security may be exchanged or surrendered without in any way impairing or affecting our liabilities hereunder without notice to us and without the necessity for any additional endorsement, consent, or guarantee by us, provided, however, that the sum guaranteed shall not be increased or decreased.

No action, event, or condition that by any applicable law should operate to discharge us from liability hereunder shall have any effect, and we hereby waive any right we may have to apply such law, so that in all respects our liability hereunder shall be irrevocable and, except as stated herein, unconditional in all respects.

For and on behalf of the Bank

Signed:_____
Date: _____
in the capacity of: *[insert: **title or other appropriate designation**]*
Common Seal of the Bank

5.b Capacity and Quality Certification Form

[RELEVANT COUNTRY AUTHORITY]

IFB NO. DATE

1 Name of the firm:

Address _____

Telephone _____ Telex _____

Telefax _____ Cable _____

a. Name of principals or owner(s):

Address _____

Telephone _____ Telex _____

Telefax _____ Cable _____

3_____ (Name of firm) is properly registered to supply pharmaceuticals or vaccines in _____(name of country), is in good legal and statutory standing with the responsible health authorities in that country, and is licensed as a primary manufacturer of the range of pharmaceuticals or vaccines to be offered. (The list of items to be offered is attached).

4 The production capacities for _____ (name of firm) follow:

The installed capacity for this firm is as follows:

Annual Capacity Non-Sterile		Annual Capacity Sterile
	Dry:	
Tablets		Vials
Capsules		Bottles
Sachets		
	_____	
Wet: (Liquids and Colloids)	Internal	
	Syrups	Tablets
	Suppositories	I.V. Fluids
	Aerosols	
	External	
	Liquids	Drops/Ointments
	Creams	
	Ointments	

5_____ (Name of firm) has manufactured and marketed the specific goods covered by this bidding document offered, for at least two (2) years, and similar goods for atleast five (5).

6_____ (Name of firm) has experience with and knowledge of modes of packaging, distribution, and transportation of pharmaceuticals or vaccines in countries similar to that of the Purchaser in terms of level of development, climate etc. The following countries have been supplied pharmaceuticals or vaccines worth equivalent to at least US$ 50,000 within the past five years:

_____
_____

7 We hereby certify that the above information is true and accurate to the best of our knowledge. We understand that the provision of information that is later found to be false is sufficient justification for disqualification.

Signature of the Officer
in relevant Country Authority _____ Date:_____
Full name (Printed) _____
Position of officer
in relevant Country Authority _____

NOTE: For items 5 & 6, certificate from the auditor of the company (not from any other CA) may also be acceptable.

6. Proforma for Performance Statement (for a period of last five years)

Bid No. _____Date of opening_____Time _____ Hours _____

Name of the Firm_____

Order placed by (full address of Purchaser) 1	Order No. and Date 2	Description and quantity of ordered goods 3	Value of order 4	Date of completion of delivery		Remarks indicating reasons for late delivery, if any 7	Was the supply of pharmaceuticals/ Consumables satisfactory* 8
				As per contract 5	Actual 6		

Signature and seal of the Bidder

_____

Countersigned by seal of Charted Accountant_____

* The Bidder shall also furnish the following documents in connection with their past performance:

For supplies within India & for Exports

a. For supplies made to public sector units in India, an Affidavit confirming that the performance statement given is correct.

b. However in case of supplies to private sector units, an affidavit confirming that the performance statement is correct along with following supporting evidence.
   i. Copy of Recent and Relevant Purchase Orders
   ii. Copy of their Invoices
   iii. Proof of Payment received from Purchasers
   iv. Documentary evidence (Client's certificate) in support of satisfactory completion of contract

7.Manufacturer's Authorization

[The Bidder shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This letter of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the Manufacturer. The Bidder shall include it in its bid, if so indicated in the BDS.]

Date: *[insert: **date** (as day, month and year) **of Bid Submission**]*
Tender No.: *[insert: **number of bidding process**]*
Alternative No.: *[insert: **identification No if this is a Bid for an alternative**]*

To: *[insert: complete name of Purchaser]*

WHEREAS

We *[insert: **complete name of Manufacturer**]*, who are official manufacturers of *[insert: **type of goods manufactured**]*, having factories at *[insert: **full address of Manufacturer's factories**]*, do hereby authorize *[insert: **complete name of Bidder**]* to submit a bid the purpose of which is to provide the following Goods, manufactured by us *[insert: **name and or brief description of the Goods**]*, and to subsequently negotiate and sign the Contract.

We hereby extend our full guarantee and warranty in accordance with Clause 15 of the General Conditions of Contract, with respect to the Goods offered by the above firm.

Signed: *[**insert: signature(s) of authorized representative(s) of the Manufacturer**]*

Name: *[insert: **complete name(s) of authorized representative(s) of the Manufacturer**]*

Title: *[insert: **title**]*

Duly authorized to sign this Authorization on behalf of: *[insert: **complete name of Bidder**]*

Dated on _____ day of _____, _____ *[insert: **date of signing**]*

8 *Acknowledgement of Receipt of Goods (for 90% Payment) in triplicate*

No. Date:

To
RITES Ltd. (MSM Division)
RITES Office Complex - 2,
Annexe Building, 4th Floor, Plot no. 144,
Sector-44, Gurgaon-122003
(HARYANA), INDIA
Fax: 91(124)2728420/2571659/2571660

This is to certify that the Goods as detailed below have been received duly inspected in good condition in accordance with the conditions of the contract and amendment if any.

Project Name	:	
Purchaser	:	
Contract i.e. NOA No. & Date	:	
Description of the goods with qty. Supplied & that comply with NOA	:	
Name of supplier	:	
Date of delivery at consignee destination site	:	
Outstanding/ dues with the Supplier as per NOA & amendment, if any	:	
		SIGNATURE OF DESIGNATED CONSIGNEE.(Medical officer/Pharmacist) Name : Designation : Seal : Contact No. : Fax No. :

Copy To (with original stamp & signature):

1. To Supplier
2. Director, NVBDCP Campus, 22 Shamnath Marg, Delhi-110054, Fax No-011 23968329

9. Final Acceptance Certificate (for last 10% payment) in triplicate

No. Date

To
RITES Ltd., (MSM Division)
RITES Office Complex - 2,
Annexe Building, 4th Floor, Plot no. 144,
Sector-44, Gurgaon-122003
(HARYANA), INDIA Fax:
91(124)2728420/2571659/2571660

Project Name	:
Purchaser	:
Contract i.e. NOA No. & Date	:
Description of Goods (Schedule No.)	:
Delivery Lot No.	:
Quantity supplied in Numbers	:
Quantity supplied in Words	:
Name of Supplier	:
Batch No(s).	:
Manufacturing Date(s)	:
Expiry Date(s)	:
Invoice No. and Date	:
Date of Final Acceptance	:

CERTIFICATE

We confirm having received _____ in good condition on _____ in accordance with the contract and entered in the Stock ledger at Page _____ on _____

Seal & Sign with Name & Designation Of the Consignee(Medical officer/Pharmacist)

Tele & Fax:

Copy To (with original stamp & signature):

1- To Supplier
2. Director, NVBDCP Campus, 22 Shamnath Marg, Delhi-110054, Fax No-011 23968329

10. AFFIDAVIT (On Stamp Paper)

I _____ son/daughter of _____ resident of _____ solemnly undertake that I am an authorized signatory of M/s _____ *(insert name of the company with full address)* and I hereby undertake that the supplies for which payments are being made have been correctly made to the respective consignees. I take full responsibility for the correctness of the documents submitted for which the payment has been claimed. I further undertake that without prejudice to the rights of purchaser as per the contract, I shall be solely responsible if any of the document is found to be fake even to make good any loss suffered by the purchaser due to incorrectness of the documents submitted by us for claiming payment against invoice(s) no(s)._____ *(insert details of invoices for which payments are being claimed) amounting to*_____.

Name: _____

Address: _____

(Supplier full address)

Witness 1 _____

Address:_____

Witness 2 _____

Address _____

Note:

1. The affidavit is to be submitted on a non judicial stamp paper of Rs 100 /-(Rupee hundred) duly notorised and to be signed by the authorized signatory of the firm.
2. This affidavit is to be submitted along with the invoices at the time of claiming 80% payment.

11. PROFORMA FOR OTHER DETAILS OF BIDDER, MANUFACTURER AND ITS BANK

1. Name & full address of the Manufacturer:

2. (a) Telephone & Fax No — Office /Works
   (b) Telex No. — Office/Works
   (c) Telegraphic address:
   (d) Email

3. Location of the manufacturing factory.

4. Name & full address of the Bidder

5. (a) Telephone/Mobile & Fax No — Office/Factory/Works
   (b) Telex No. — Office/Works
   (c) Telegraphic address:
   (d) Email

6. Details of two Persons that RITES Ltd. may contact for requests for clarification during bid evaluation:

	1st	2nd
(i) Name: (ii) Tel number (direct): (iii)Mobile No. (iv) Email address		

7. Bank details from where the Bank Guarantee for Bid Security has been issued:

(i) Name and address of the Bank:
(ii) For a foreign bank, name of correspondent Bank in India:
(iii) Name of the contact Person
(iv) Phone number/Mobile
(v) Fax Number
(vi) Email address

Signature and seal of the Bidder

12. INTEGRITY PACT

Between
RITES LTD. acting for and on behalf of and as an Agent / Power of Attorney Holder of _____hereinafter called the "Purchaser" AND
_____ hereinafter referred to as "The Bidder/Suplier"

Preamble

The Purchaser intends to award, under laid down organizational procedures, contract/s for _____. The Purchaser values full compliance with all relevant laws and regulations, and economic use of resources, and of fairness and transparency in his relations with the Bidder/s and/or Supplier/s.

In order to achieve these goals, the Purchaser will appoint an Independent External Monitor (IEM) who will monitor the Tender process and execution of the contract for compliance with the principles mentioned above.

Section 1 – Commitments of the Purchaser

(1) The Purchaser commits himself to take all measures necessary to prevent corruption and to observe the following principles:-

1. No employee of the Purchaser, personally or through family members, will in connection with the tender or for the execution of the contract, demand, take a promise for or accept, for self or third person, any material or immaterial benefit which the person is not legally entitled to.

2. The Purchaser will, during the tender process, treat all Bidders with equity and reason. The Purchaser will in particular, before and during the tender process, provide to all Bidders the same information and will not provide to any Bidder confidential/additional information through which the Bidder could obtain an advantage in relation to the tender process or the contract execution.

3. The Purchaser will exclude from the process all known prejudiced persons.

(2) If the Purchaser obtains information on the conduct of any of his employees which is a criminal offence under the IPC (Indian Penal Code) /PC (Prevention of Corruption) Act, or if there be a substantive suspicion in this regard, the Purchaser will inform its Chief Vigilance Officer and in addition can initiate disciplinary action.

Section 2 – Commitments of the Bidder/Supplier

(1) The Bidder/Supplier commits himself to take all measures necessary to prevent corruption. He commits himself to observe the following principles during his participation in the tender process and during the contract execution.

1. The Bidder/Supplier will not directly or through any other person or firm, offer, promise or give to any of the Purchaser's employees involved in the tender process or the execution of the contract or to any third person any material or other benefit which he is not legally entitled to, in order to obtain in exchange any advantage of any kind whatsoever during the tender process or during the execution of the contract.

2. The Bidder/Supplier will not enter with other Bidders into any undisclosed agreement or understanding, whether formal or informal. This applies in particular to prices, specifications, certifications, subsidiary contracts, submission or non-submission of bids or any other actions, to restrict competitiveness or to introduce cartelization in the bidding process.

3. The Bidder/Supplier will not commit any offence under the relevant IPC/PC Act; further the Bidder/ Supplier will not use improperly, for purposes of competition or personal gain, or pass on to others, any information or document provided by the Purchaser as part of the business relationship, regarding plans, technical proposals and business details, including information contained or transmitted electronically.

4. The Bidder/Supplier will, when presenting his bid, disclose any and all payments he has made, is committed to or intends to make to agents, brokers or any other intermediaries in connection with the award of the contract.

(2) The Bidder/ Supplier will not instigate third persons to commit offences outlined above or be an accessory to such offences.

Section 3-Disqualification from tender process and exclusion from future contracts

If the Bidder/Supplier, before award or during execution has committed a transgression through a violation of Section 2 above, or in any other form such as to put his reliability or credibility in question, the Purchaser is entitled to disqualify the Bidder/Supplier from the tender process or take action as per the procedure mentioned in the "Guideline on banning of business dealing" annexed and marked as **Annexure "A**".

Section 4- Compensation for Damages

(1) If the Purchaser has disqualified in terms of the provisions in Section 3, the Bidder/Supplier from the tender process prior to the award of contract, the Purchaser is entitled to demand and recover the damages equivalent to Earnest Money Deposit/ Bid Security.

(2) If the Purchaser has terminated the contract during execution in terms of the provisions under Section 3, the Purchaser shall be entitled to demand and recover from the Supplier the damages equivalent to Performance Security.

Section -5 Previous transgression

(1) The Bidder/ Supplier declares that no previous transgression occurred in the last 3 years with any other Company in any country conforming to the Anti-Corruption approach or with any other Public Sector Enterprise in India that could justify his exclusion from the tender process.

(2) If the Bidder/Supplier makes incorrect statement on this subject, he can be disqualified from the tender process or action can be taken as per the procedure mentioned in "Guideline on banning of business dealing".

Section -6 Equal treatment of all Bidders/Suppliers

(1) The Bidder/Supplier undertakes to demand from all partners (if permitted under the conditions/ clauses of the contract) a commitment to act in conformity with this Integrity Pact and to submit it to the Purchaser before signing the contract.

(2) The Bidder/ Supplier confirms that any violation by any of his partners to act in conformity with the provisions of this Integrity Pact can be construed as a violation by the Bidder/Supplier himself, leading to possible Termination of Contract in terms of Section 4.

(3) The Purchaser will disqualify from the tender process all bidders who do not sign this Pact or violate its provisions.

Section 7- Criminal charges against violating Bidders/Suppliers

If the Purchaser obtains knowledge of conduct of a Bidder, Supplier or Partners, or of an employee or a representative or an associate of a Bidder, Supplier, which constitutes corruption, or if the Purchaser has substantive suspicion in this regard, the Purchaser will inform the same to its Chief Vigilance Officer.

Section -8 Independent External Monitor/Monitors

(1) The Purchaser shall appoint competent and credible Independent External Monitor for this Pact. The task of the Monitor is to review independently and objectively, whether and to what extent the parties comply with the obligations under this agreement.

(2) The Monitor is not subject to instructions by the representatives of the parties and will perform his functions neutrally and independently. He will report to the MD/RITES Ltd.

(3) The Bidder/Supplier accepts that the Monitor has the right of access without restriction to all Project documentation of the Purchaser including that provided by the Supplier. The Supplier will also grant the Monitor, upon his request and demonstration of a valid interest, unrestricted and unconditional access to his project documentation. The same is applicable to Partners. The Monitor is under contractual obligation to treat the information and documents of the Bidder/Supplier/Partners with confidentiality.

(4) The Purchaser will provide to the Monitor sufficient information about all meetings among the parties related to the Project provided such meetings could have an impact on the contractual relations between the Purchaser and the Supplier. The parties offer to the Monitor the option to participate in such meetings.

(5) As soon as the Monitor notices or has reason to believe that violation of the agreement by the Purchaser or the Bidder/ Supplier, has taken place, he will request the Party concerned to discontinue or take corrective action, or to take any other relevant action. The Monitor can in this regard submit non-binding recommendations. Beyond this, the Monitor has no right to demand from the parties that they act in a specific manner or refrain from action or tolerate action.

(6) The Monitor will submit a written report to the MD/RITES Ltd. within 8-10 weeks from the date of reference or intimation to him by the Purchaser and should the occasion arise, submit proposal for correcting problematic situations.

(7) If the Monitor has reported to the MD/RITES Ltd. of a substantiated suspicion of an offence under relevant IPC/PC Act, and the MD/RITES Ltd. has not, within reasonable time, taken visible action to proceed against such offender or reported it to the Chief Vigilance Officer, the Monitor may also transmit this information directly to the Central Vigilance Commissioner.

(8) The word Monitor would include both singular and plural.

Section – 9 Pact Duration

This pact begins when both parties have legally signed it. It expires for the Supplier when his Security Deposit is released on completion of the contractual obligation.

If any claim is made/lodged during this time the same shall be binding and continue to be valid despite the lapse of this pact specified above, unless it is discharged/determined by MD/RITES Ltd.

Section 10 Other Provisions

(1) This agreement is subject to Indian Law. Place of performance and jurisdiction shall be as stated in the ContractAgreement.

(2) Changes and supplements as well as termination notices need to be made in writing.

(3) If the Supplier is a partnership or a consortium, this agreement must be signed by the Partner in charge/ Lead Member nominated as being incharge and who holds the Power of Attorney signed by legally authorised signatories of all the partners/Members. The Memorandum of Understanding /Joint Venture Agreement will incorporate a provision to the effect that all Members of the Consortium will comply with the provisions in the Integrity Pact to be signed by the Lead Member on behalf of the Consortium. Any violation of Section 2 above by any of the Partners/Members will be construed as a violation by the consortium leading to possible Termination of Contract in terms of Section 3.

(4) Should one or several provisions of this agreement turn out to be invalid, the remainder of this agreement remains valid. In this case, the parties will strive to come to an agreement to their original intentions.

RITES Ltd.
Agent / Power of Attorney Holder
(For & on behalf of the Purchaser) (For the Bidder/Supplier)

(Office Seal) (Office Seal)

Place:……
Date:…….

Witness 1:

(Name & Address) ----------

Witness 2

(Name & Address) ----------

---

13. CHECKLIST

(All the pages of the bid should be Serial Numbered & signed/initialled)

Sl. No.		Activity	Yes/No/ NA	Page No. in the Bid
1	(a)	**Bid Security** for required amount		
	(b)	Bid Security in the form of		
	(i)	*Bank Guarantee as per format in Bidding document issued by Indian Bank*		
	(ii)	*Draft or Banker's cheque issued by Indian Nationalised bank*		
	(c)	Validity Date of Bid Security (**Valid up to 45-days beyond the bids validity) as specified in ITB Data Sheet clause18.2**)		
	(d)	Amendment in Bid Security (if any)		
2		**The Bank details from where the Bank Guarantee has been issued along with Phone, fax numbers and email Ids. For Banks from outside India the details of the countersigning Bank in India.**		
3	(a)	**Bid Form** duly signed		
	(b)	**Power of Attorney** in favour of the signatory		
4		The **manufacturer's authorization** form in Form 7 of Section V		
5		**Documents establishing post qualification (ITB 6)**		
(a)		**Certificate of incorporation** of Manufacturer		
(b)		**Manufacturing Licence** of the good(s) quoted in bid		
(c)		**Proof of Exp in manufacturing & marketing** of **specific goods covered by the bidding document for at least two (2) years in the last five (5) years**, Indicate Serial No. in performance statement		
(d)		**Proof of experience in manufacturing & marketing** of **similar goods** for at least three (3) years in the last five (5) years, Indicate Serial Nos. in performance statement		
(e)		Performance statement as per required Proforma, along with **supporting documents viz. (i) Copy of Purchase Orders,(ii) Copy of Invoices, (iii) Proof of Payment received from Purchasers & (iv) Documentary evidence (Client's certificate) in support of satisfactory completion of contract (for concerned PO's).**		
(f)		WHO/GMP valid on the date of opening of Bid		
(g)		COPP certificates of the specific item, valid on the date of opening of bid.		
(h)		Certificate of having **achieved Annual production** of equivalent product for last five years by CA and supported by **audited Annual Report.**		
(i)		Copies **complete set of audited financial statements** of accounts (including balance sheet, profit and loss account, auditor's reports and IT returns) certified by the auditor of the Company for last three financial years		
(j)		Indicate Sr. No. in **performance statement** which establishes the post qualification criteria of completing one similar contract in last five years		
(k)		Certificate by CA of annual turnover for last 3 (three) financial years		
6		Documents to establish that **product is registered in India** as per ITB clause 5.2 if applicable		
7 a.		Details of **onsite quality control laboratory facilities and services and range of test conducted.**		
7 b.		Capacity and Quality certification form in the format provided in the Bidding document		
8		**Affidavit to disclosure** about any instance of **debarment/blacklisting by state or central Govt. Health organisation**		
9		**Statement of installed manufacturing capacity c**ertified by appropriate authority		
10		**No deviation statement on technical specification**		
11		**Check list of technical specification**		
12	(a)	**Agreement with all terms and condition of the bid document**		
	(b)	If no, have you indicated deviations		
13	(a)	**Mentioned Price in the appropriate Proforma**		
	(b)	**Conditional or unconditional discount** mentioned in the bid (if any)		

Sl. No.		Activity	Yes/No/ NA	Page No. in the Bid
14		Copies of original documents defining the constitution or **legal status, place of registration, and principal place of business; for both manufacturer & non manufacturer**		
15		**Undertaking** as per clause ITB 6 (C)(b) {The **bidder** and the **manufacturer** whose product is offered by the bidder shall disclose instance of previous past performance of his and the manufacturer whose product is procured by the bidder, that may have resulted into adverse actions taken against the bidder during the last two years. Such adverse actions taken against the bidder or manufacturer may be treated as unsatisfactory performance history while deciding the award of contract. **If no adverse action has been taken against the Bidder, the Bidder must provide a statement in its** bid saying that there has been no such previous past performance resulting in adverse actions being taken against him.}		
16	(a)	The bidder shall provide an **undertaking** that: The **proprietor/promoter/director of the firm, its employee, partner or representative is not convicted by a court of law** following prosecution for offence involving moral turpitude in relation to business dealings including malpractices such as bribery, corruption, fraud, substitution of bids, interpolation, misrepresentation, evasion, or habitual default in payment of tax levied by law; etc.		
	(b)	The firm **does not employ a government servant, who has been dismissed or removed on account of corruption**.		
17		**List of products being manufactured** by the bidder with product registration/ **license number and date**.		
18		Form 11: Proforma for other details of Bidder, Manufacturer and its Bank		
		Form 12: Integrity Pact		
19		The following details shall also be provided by Indian Bidders:		
	a.	Name, address, PAN. and Income Tax details (ward/circle where they are being assessed) of the Directors of the Bidding Company.		
	b.	Company's PAN and Income Tax details and ward/circle where it is being assessed,		
	c.	Registration details of the company under VAT, local and Central Sales Tax, and other laws as may be applicable and also Sales tax/VAT clearance certificate.		