STATE PHARMACEUTICALS MANUFACTURING CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act. No. 49 of 1957)

(IFB REF. : SPMC/01/2024)

BID DOCUMENT FOR

PROCUREMENT OF PHARMACEUTICAL RAW MATERIALS

State Pharmaceuticals Manufacturing Corporation of Sri Lanka.
11, Sir John Kotalawala Mawatha
Kandawala Estate
Ratmalana
Sri Lanka.

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SECTION I. INSTRUCTIONS TO BIDDERS

A. INTRODUCTION

1. Scope of Bid

1.1. The Purchaser, as specified in the Bid Data Sheet and in the Special Conditions of Contract (SCC), invites bids for the supply of Pharmaceuticals Raw Materials described in the Schedule of Requirements. The name and invitation for Bid number (IFB) of the Contract is provided in the Bid Data Sheet and in the SCC.

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

2. Source of Funds

Goods will be financed as specified in **Bid Data Sheet**.

B. THE BIDDING DOCUMENT

3. Content of the Bidding Documents

3.1 The Bidding Documents are those stated below and should be read in conjunction with any Addendum issued in accordance with ITB Clause 6.

- Section I. Instructions to Bidders (ITB)
- Section II. Bid Data Sheet (BDS)
- Section III. General Conditions of Contract (GCC)
- Section IV. Special Conditions of Contract (SCC)
- Section V. Sample Forms (including Contract Agreement & Supplier Approval Questionnaire)
- Section VI. Schedule of Requirements

3.2 The Purchaser is not responsible for the completeness of the Bidding Document and its Addenda, if they were not obtained directly from the Purchaser.

3.3 The Bidder is expected to examine all instructions, forms, terms, and specifications in the Bidding Document. Failure to furnish all information or documentation required by the Bidding Document, may result in the rejection of the Bid.

4. Eligibility

4.1 Except as provided in ITB Sub-Clause 4.2, this bidding process is **open to:**

a. those prequalified firms, as defined in the Bid Data Sheet or schedule of requirement, where a prequalification process has been undertaken for the Contract(s) for which these Bidding Documents have been issued, or

b. **all** firms, as defined in the edition specified by the Bid Data Sheet or schedule of, where a prequalification process has not been undertaken for the contract(s) for which these Bidding Documents have been issued.

4.2 Except suppliers who are black listed by the Purchaser or Purchaser's country are eligible for the bidding as mention in Bid Data sheet or schedule of requirement.

5. Clarification of Bidding Document

A Prospective Bidder requiring any clarification of the Bidding Document shall contact the Purchaser in writing at the Purchaser's address indicated in the **BDS**. The Purchaser will respond in writing to any request for clarification, provided that such request is received no later than twenty-one (21) days prior to the deadline for submission of Bids. The Purchaser shall forward copies of its response to all Bidders who have acquired the Bidding Document directly from it, including a description of the inquiry but without identifying its source. Should the Purchaser deem it necessary to amend the Bidding Document as a result of a clarification, it shall do so following the procedure under ITB 6 and 16.2

6. Amendment of Bidding Document

6.1 At any time prior to the deadline for submission of the Bids, the Purchaser may amend the Bidding Document by issuing Addenda.

6.2 Any addendum issued shall be part of the Bidding Document and shall be communicated in writing to all who have obtained the Bidding Document directly from the Purchaser. 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.

6.3 To give prospective Bidders reasonable time in which to take an addendum into account in preparing their Bids, the Purchaser may, at its discretion, extend the deadline for the submission of the Bids, pursuant to ITB 16.2

C. PREPARATION OF BIDS

7. Cost of Bidding

The Bidder shall bear all costs associated with the preparation and submission of its Bid, and the Purchaser shall not be responsible or liable for those costs, regardless of the conduct or outcome of the bidding process.

8. Language of Bid

The Bid, as well as all correspondence and documents relating to the Bid exchanged by the Bidder and the Purchaser, shall be written in the language specified in the **BDS**. Supporting documents and printed literature that are part of the Bid may be in another language provided they are accompanied by an accurate translation of the relevant passages in the language specified in the **BDS**, in which case, for purposes of interpretation of the Bid, such translation shall govern.

9. Documents Constituting the Bid

9.1. The bid submitted by the Bidder shall comprise the following:

(a) Duly filled Bid form & Statement of compliance, in accordance with the forms indicated in Section V; (This statement of compliance must be completed without any alteration to its format and no substitutes shall be accepted. All blank spaces shall be filled in with the information requested.)

(b) original form of bid security in accordance with the provisions of ITB 13(Bid Security);

(c) Duly filled Manufacturer Authorization Form

(d) alternative offers, at the Bidder's option, when permitted;

(e) written power of attorney or letter of authorization with a copy of Certified Resolution by the board of directors of the bidding company authorizing the signatory of the bid to commit the Bidder;

(f) In the case of New Bidders including those who have not previously supplied the bidding item to the purchaser successfully – Duly filled "Supplier Approval Questionnaire" should be forwarded with the Bids. Also new Bidders must submit Raw material samples as per requested in the **Bid Data Sheet**

Or

In case of prequalified bidder, the Bidder shall submit related updated information between the date of pre-qualification up to the submission of bids in accordance with supplier approval questionnaire. (Only If happen major changes in Manufacturer)

(g) any other documentation as requested in the **Bid Data Sheet.**

10. Alternative Bids

Unless otherwise indicated in the **BDS**, alternative bids shall not be considered.

11. Currencies of Bid

11.1 Bidder may express their bid price in any fully convertible currency. If a Bidder wishes to be paid in a combination of amounts in different currencies, it may quote its price accordingly but shall use no more than three currencies in addition to the currency of the Purchaser's country.

11.2 Bidders for the supply of goods manufactured in the purchaser's Country shall be quoted in currency of the Purchaser's country.

12. Period of Validity of Bids

12.1 Bids shall remain valid for the period specified in the **BDS** after the bid submission deadline date prescribed by the Purchaser. A Bid valid for a shorter period shall be rejected by the Purchaser as nonresponsive.

12.2 In exceptional circumstances, prior to the expiration of the bid validity period, the Purchaser may request Bidders to extend the period of validity of their Bids. The request and the responses shall be made in writing. If a Bid Security is requested in accordance with ITB 13, it shall also be extended for a corresponding period. A Bidder may refuse the request without forfeiting its Bid Security. A Bidder granting the request shall not be required or permitted to modify its Bid.

13. Bid Security

13.1 Unless otherwise specified in the **Bid Data Sheet,** the Bidder shall furnish, as part of its bid, a bid security (as per format in section V) in the amount stipulated in the **Bid Data Sheet & Schedule of requirement** in the currency of the Purchaser's country, or the equivalent amount in a freely convertible currency.

13.2 The bid security shall remain valid for a period of 28 days beyond the validity period for the bid.

13.3 Bid security mentioned by **Bid Data Sheet** are acceptable.

13.4 The Bid Security of the successful Bidder shall be returned as promptly as possible once the successful Bidder has signed the Contract Agreement and furnished the required Performance Security.

13.5 The Bid Security may be forfeited:

a. If a Bidder withdraws its Bid during the period of bid validity specified by the Bidder on the Bid Submission Sheet, except as provided in ITB 12.2; or

b. If the successful Bidder fails to:

I. Sign the Contract in accordance with ITB 29

II. Furnish a performance Security in accordance with ITB 30; or.

III. Accept the arithmetical correction in accordance with ITB 22.

14. Format and Signing of Bid

14.1 The Bidder shall prepare an original and the number of copies/sets of the bid indicated in the **Bid Data Sheet,** 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.

14.2 The original and all copies of the bid, each consisting of the documents listed in ITB Sub-Clause 9.1, 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. The later authorization shall be indicated by written power of attorney or letter of authorization, which pursuant to ITB Sub-Clause 9.1 (e) shall accompany the bid.

14.3 Any interlineation, erasures, or overwriting to correct errors made by the Bidder should be initialed by the person or persons signing the bid.

14.4 The Bidder shall furnish in the Bid Form (a sample of which is provided in the Sample Forms Section-V 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 AND OPENING OF BIDS

15. Sealing and Marking of Bids

15.1 The Bidder shall enclose the original and each copy of the bid including alternative bids, if permitted in accordance with ITB Clause 10, 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.

15.2 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 in the **Bid Data Sheet;**

c) bear the specific identification of this bidding process indicated in the **Bid Data Sheet,** the Invitation for Bids (IFB) title and number indicated in the **Bid Data Sheet;** and

d) bear a statement "DO NOT OPEN BEFORE [date and time]" to be completed with the time and date specified in the Bid Data Sheet relating to ITB Sub-Clause 16.1.

15.3 If the outer envelope is not sealed and marked as required by ITB Sub-Clause 15.2, the Purchaser will assume no responsibility for the misplacement or premature opening of the bid.

16. Deadline for Submission of Bids

16.1 Bids must be received by the Purchaser at the address specified in the **Bid Data Sheet** relating to ITB Sub-Clause 15.2 (b) no later than the time and date specified in the **Bid Data Sheet.**

16.2 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 6.3, 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.

17. Late Bids

Any bid received by the Purchaser after the deadline for submission of bids prescribed by the Purchaser in the **Bid Data Sheet** pursuant to ITB Clause 16 will be rejected and returned unopened to the Bidder.

18. Withdrawal, Substitution, and Modification of Bids

18.1 Bidder may withdraw, substitute, or modify its Bid after it has been submitted by sending a written Notice, duly signed by an authorized representative, and shall include a copy of the authorization in accordance with ITB 14.2 (except that Withdrawal Notices do not require copies). The corresponding substitution or modification of the Bid must accompany the respective written Notice. All Notices must be:

a. submitted in accordance with ITB Clauses 14 and 15 (except that Withdrawal Notices do not require copies), and in addition, the respective envelopes shall be clearly marked "Withdrawal," "Substitution," "Modification"; and

b. received by the Purchaser prior to the deadline prescribed for submission of bids, in accordance with ITB 16.

18.2 Bids requested to be withdrawn in accordance with ITB 18.1 shall be returned unopened to the Bidders.

19. Bid Opening

19.1 The Purchaser will open all bids, including withdrawal notices and modifications, in public, in the presence of Bidders' representatives who choose to attend, at the time, on the date, and at the place specified in the Bid Data Sheet. Bidders' representatives shall sign a register as proof of their attendance.

19.2 First, envelopes marked "WITHDRAWAL" shall be opened, read out, and recorded, and the envelope containing the corresponding Bid shall not be opened, but returned to the Bidder. If the withdrawal notice is not accompanied by a copy of the valid authorization pursuant to ITB 14.2, the withdrawal shall not be permitted and the corresponding Bid will be opened. Next, envelopes marked "SUBSTITUTION" shall be opened, read out, recorded, and exchanged for the corresponding Bid being substituted, and the substituted Bid shall not be opened, but returned to the Bidder. No Bid shall be substituted unless the corresponding Substitution Notice contains a valid authorization to request the substitution and is read out and recorded at bid opening. Envelopes marked

"MODIFICATION" shall be opened, read out, and recorded with the corresponding Bid. No Bid shall be modified unless the corresponding Modification Notice contains a valid authorization to request the modification and is read out and recorded at bid opening. Only envelopes that are opened, read out, and recorded at bid opening shall be considered further.

19.3 All other envelope shall be opened at a time, and the Officer who opens the Bids will read out (or cause to be read out) to those present, the name of each Bidder as well as the amount quoted together with discounts, if any. Whether a Bid security has been submitted or not shall also be announced. Details of the make-up of any Bid will not be read out.

E. EVALUATION AND COMPARISON OF BIDS

20. Confidentiality

20.1 Information relating to the examination, evaluation, comparison, and post qualification of Bids, and recommendation of contract award, shall not be disclosed to Bidders or any other persons not officially concerned with such process until notification of contract award is made to all bidders.

20.2 Any attempt by a Bidder to influence the Purchaser in the examination, evaluation, comparison, and post qualification of the Bids or Contract award decisions may result in the rejection of its Bid.

20.3 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 may do so in writing.

21. Clarification of Bids

To assist in the examination, evaluation, comparison and post-qualification of the Bids, the Purchaser may, at its discretion, ask any Bidder for a clarification of its Bid. Any clarification submitted by a Bidder with regard to its Bid and that is not in response to a request by the Purchaser shall not be considered. The Purchaser's request for clarification and the response shall be in writing. No change in the prices or substance of the Bid shall be sought, offered, or permitted, except to confirm the correction of arithmetic errors discovered by the Purchaser in the evaluation of the Bids, in accordance with ITB 22.

22. Correction of Arithmetical Errors

22.1. The Purchaser will examine the bids after opening, in order to ensure the correctness of the Bids. Arithmetical errors if any, will be corrected on the following basis. If a Bidder does not accept the correction of errors, its bid will be rejected and its bid security may be forfeited.

(a) If discrepancy is between unit price and total price, then the unit price shall prevail and the total price will be corrected. Unless there is an obvious gross misplacement of the decimal point in the unit rate, in which case the line item total as quoted will govern, and the unit rate will be corrected.

(b) If discrepancy is between word and figures, the amount in word will prevail.

(c) If a discrepancy appears between the original bid and the duplicate, the original will prevail.

23. Conversion to Single Currency

23.1 To facilitate evaluation and comparison, the Purchaser will convert all bid prices expressed in the various currencies in to the currency of the Purchaser's country at the selling exchange rate established for similar transactions by the Central Bank in the Purchaser's country.

24. Evaluation of Bids

In addition to the price, conformity with the specifications, test results of the samples, nature and the quality of the past supplies and performance, Bid security, which are the current criteria, time schedule and responsiveness to the terms and conditions of the bid will also be taken into consideration with regard to the evaluation of bids.

F. AWARD OF CONTRACT

25. Award Criteria

Purchaser keeps the right to award partial quantities, request extra certificates from independent laboratories, extra samples, pre-shipment samples, and or may request 60 days DA terms without a price change for "Critical Items" from the bidders who had not been "previous successful suppliers". E.g.-If a supplier had been successful in

supplying item ’A’ that supplier is considered as a ‘previous successful supplier’ only for item ‘A’

26. Purchaser’s Right to Accept Any Bid and to Reject Any or All Bids

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.

For various reasons Purchaser may have to cancel orders placed by fax or indent or letter. Therefore, Purchaser reserves the right to cancel order or indents for quantities where a firm L/C has not been established.

27. Purchaser’s Right to Vary Quantities at Time of Award

27.1 The Purchaser reserves the right at the time of Contract award to increase or decrease, by the percentage indicated in the **Bid Data Sheet,** the quantity of goods and services beyond that originally specified in the Schedule of Requirements without any change in unit price or other terms and conditions.

28. Notification of Award

28.1 Prior to the expiration of the period of bid validity, the Purchaser shall notify the successful Bidder, in writing, that its Bid has been accepted.

28.2 Until a formal Contract is prepared and executed, the notification of award shall constitute a binding Contract.

29. Signing of Contract

29.1 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.

29.2 Within twenty-eight (28) days of receipt of the Contract Agreement, the successful Bidder shall sign, date, and return it to the Purchaser.

30. Performance Security

30.1 Within twenty-eight (28) 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 in another form acceptable to the Purchaser.

30.2 Failure of the successful Bidder to comply with the requirement of ITB Clause 29 or ITB Sub-Clause 30.1 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.

SECTION II. BID DATA SHEET

Bid Data Sheet

The following specific data for the Goods to be procured shall complement, supplement, or amend the provisions in the Instructions to Bidders (ITB). Whenever there is a conflict, the provisions in the Bid Data Sheet (BDS) shall prevail over those in the ITB.

A. General	
ITB 1.1	Name of Purchaser: State Pharmaceuticals Manufacturing Corporation **About Purchaser**: The State Pharmaceuticals Manufacturing Corporation of Sri Lanka (SPMC) is a fully Sri Lanka government owned organization engaged in the manufacturing of Pharmaceuticals for its own stock and distribution in the private sector, and for use in all government hospitals of the Department of Health. The procurement of pharmaceutical raw materials and laboratory chemicals etc, is done by the SPMC for the manufacturing of pharmaceuticals. Sealed Bids are invited from foreign and local manufacturers /suppliers or their accredited agents for the supply of the items indicated in schedule of Supply. Bidders could quote for one or more items indicated in the Schedule of requirement.
ITB 1.1	Name of the contract: Supply of Pharmaceutical Raw Materials
ITB 1.1	IFB Number: SPMC/01/2024
ITB 2	Goods will be financed by the State Pharmaceuticals Manufacturing Corporation.
ITB 3	This Bidding process is open to: All the suppliers (International Competitive Bidding) as mentioned in Schedule of Requirement.
B. Biding Document	
ITB 5	For **clarification purposes only**, the Purchaser's address is: Attention: DGM- Planning & Procurement Address: State Pharmaceuticals Manufacturing Corporation No. 11, Sir John Kotalawala Road, Kandawala Estate Ratmalana. Country: Sri Lanka Telephone: +94-11-2637574,+94-11-2635353 Facsimile number: +94-11-2626621 Electronic mail address: chairman@spmc.gov.lk

C. Preparation of Bids	
ITB 8	The language of the Bid is: The Bid, as well as all correspondence and documents relating to the Bid exchanged by the Bidder and the SPMC, shall be written in **English language.**
ITB 9 (g)	In addition to the documents stated in Paragraphs 9 (a) through (f), the following documents must be included with the Bid: N/A
ITB 9 (f)	**SAMPLES** (i) Representative samples in respect of items offered should be submitted to reach us on or before the deadline of submission of Bids. (ii) The bidders who supplied material from a manufacturer during past two years and its' performance has been satisfied, then it is not required to submit samples at the closing time of the tender. However, samples shall be submitted by the bidders on the request of State Pharmaceuticals Manufacturing Corporation, as per the expert opinion on the consistency of the performance and analysis reports of the materials from the same manufacturer. (iii) All prospective bidders are advised to submit their samples through their local agents to ensure compliance with this request. (iv) If the Bidder does not have a local agent then samples should be sent to "STATE PHARMACEUTICALS MANUFACTURING CORPORATION OF SRI LANKA, 11 ,Sir John Kotalawala Mawatha, Kandawala Estate, Ratmalana, Sri Lanka. A "No-Commercial Value Invoice" (indicating nominal value for custom's purpose only) together with analytical certificates should be attached to the consignee's copy of Air Waybill and a copy should also be sent direct to the State Pharmaceuticals Manufacturing Corporation, 11 Sir john Kotalawala Mawatha, Kandawala Estate, Ratmalana, Sri Lanka. All these documents and all sample packs should bear the IFB number (without which the Customs will not permit clearance.) (v) **Two samples in equal quantities (sufficient quantity for analysis) to be submitted for each item with the offer as one will be tested and the other be kept as a reference sample. Such samples submitted for each item should be from the same batch.** (vi) All samples should be properly labeled in the English language and the label must specify **only the "IFB Number", and "Name of the item".** Please submit samples along with a "**Covering Letter**" and the relevant **"Original Certificate of Analysis"**. The name of the item, batch number, date of manufacture, date of expiry, shelf life and name

	and address of the manufacturer should be indicated in the "Original Certificate of Analysis" in addition to other relevant details. Samples without **"Original Certificate of Analysis"** may not be tested and such offer may not be considered. **Any of the above details should not be inserted in to the sample material.** (vii) Sample shall not be submitted enclosed in the Bid package. Sample shall submit separately before the deadline of submission of the Bids.
ITB10	Alternative Bids . . . . permitted *(Note:If alternative offers are permitted, the Bidder should mark the Bids as "Original Offer" and "Alternative Offer". Each individual offer should carry a separate bid Security. If these requirements are not met, bid that covered by the Bid Security will be accepted and scheduled. (Only the lower priced Bid).*
ITB 12	The bid validity period shall be **91** days after the deadline for bid submission.
ITB 13.1	The Bidders shall furnish an unconditional bid security either in the form of a guarantee encashable on first written demand to the value stated against each item, as per the schedule of requirement. No foreign Government Organizations are exempted from this requirement. Bid security shall be submitted either together with the bid or to reach us on or before the closing of Bid. Bids without bid security, (where necessary) will be rejected. The bid security shall be in the form of an unconditional guarantee issued by an approved commercial bank operating in Sri Lanka. The bid security should be valid for at least 28 days **beyond** the validity of the offer.
ITB 13.3	Bid security issued by the following Institutions are acceptable:- 1. a. A Commercial bank operating in Sri Lanka, approved by the Central Bank of Sri Lanka. b. A bank based in another country but the security or guarantee "Confirmed" by a commercial bank operating in Sri Lanka mentioned in "a" above. c. A letter of credit issued by a foreign bank, but "Confirmed" by a Commercial Bank operating in Sri Lanka mentioned in "a" above. d. Any other agency approved by the treasury from time to time. e. Bid security shall be submitted in favor of Chairman – State Pharmaceuticals Manufacturing Corporation, No.11, Sir John Kothalawala Mw, Kandawala Estate, Ratmalana, Sri Lanka

	Securities and guarantees shall be unconditionally encashable, on the receipt of first written request from the executing agency (on demand securities and guarantees) In addition to the above, the following can also be accepted. 1. Cash deposit 2. Bank draft Personal cheque or company cheque are **not accepted** as bid security.
ITB 14.1	In addition to the original of the Bid, the number of copies is: **01**
	D. Submission and Opening of Bids
ITB 15	Bids shall be submitted in one original and one Copy sealed separately and marked as 'Original' and 'Copy' respectively. Both envelopes shall together be enclosed in one envelope sealed and addressed to Chairman – Procurement Committee, State Pharmaceuticals Manufacturing Corporation, No.11, sir John Kothalawala Mw, Kandawala Estate, Ratmalana, Sri Lanka. Offers which are not accompanied by Copy and not giving item numbers are liable to be rejected. In the event of any discrepancy between the original and the copies, the original shall prevail. Bidder may always submit their bids by Post or by hand delivery. Bidders, if sent through the Post should be sent under registered cover. The Bidder or his agent may also personally deposit sealed Bids in the Tender Box kept for this purpose at the State Pharmaceuticals Manufacturing Corporation, Ratmalana. The left-hand top-corner of the envelope should indicate the IFB number and the closing date of Bid. Bids should be received on or before the closing date & time of Bid. Late Bids will not be entertained under any circumstances and will be unopened & returned to Bidders. The SPMC shall **NOT** accept responsibility for the Bid misplacement or premature opening of offers if the cover has not been marked as given above.
ITB 15.2(b)	For **bid submission purposes** only, the Purchaser's address is : Attention : Chairman – Procurement Committee, State Pharmaceuticals Manufacturing Corporation, Street Address : No.11, Sir John Kothalawala Mw, Kandawala Estate, City: Ratmalana, Country: Sri Lanka

ITB16.1	**The deadline for bid submission is:** Date : 26.03.2024 Time : 10.00 a.m.
ITB 19.1	**The bid opening shall take place at:** Place: State Pharmaceuticals Manufacturing Corporation, Street Address : No.11, sir John Kothalawala Mw, Kandawala Estate, City: Ratmalana, Country: Sri Lanka Date : 26.03.2024 Time: 10.00 a.m.
E. Evaluation, and Comparison of Bids	
ITB 23	Bid prices quoted in different currencies shall be converted into : The source of the selling exchange rate shall be : The date for the selling exchange rate shall be :
F. Award of Contract	
ITB 27	The corporation reserves the right, at time of award to increase or decrease the quantity required, by 25% without any change in price or other terms and conditions. Where a supplier is Bidding for a product which has not been supplied before, the Procurement Committee reserves the right to purchase only part of the quantity from such supplier, and to purchase the balance quantity from another manufacturer who has successfully supplied same item previously. However, in such cases the price offered by such supplier for the total amount should be maintained for the smaller quantity.

SECTION III. GENERAL CONDITIONS OF CONTRACT

1. Definitions

1.1 Unless the context otherwise required, capitalized terms used in this Contract and the ancillary documents, shall have the meaning ascribed to each of them herein below:

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

(e) "The Goods" means all of the pharmaceuticals raw materials that the Supplier is required to supply to the Purchaser under the Contract.

(f) "The Purchaser" means the organization purchasing the Goods, as **named in the SCC.**

(g) "The Purchaser's country" is the country **named in the SCC.**

(h) "SCC" means the Special Conditions of Contract.

(i) "The Supplier" means the individual or firm supplying the Goods and Services under this Contract, as **named in the SCC.**

(j) "SPMC" means the State Pharmaceuticals Manufacturing Corporation of Sri Lanka.

2. Application

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

3. Standards

3.1. The Goods supplied under this Contract shall conform to the standards & Specifications mentioned in the schedule of requirement 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.

4. Patent Rights.

4.1. 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 the Purchaser's country.

5. Performance Security

5.1. Within twenty-eight (28) days of receipt of the notification of Contract award, the successful Bidder shall furnish to the Purchaser the performance security in the amount **specified in the SCC.**

5.2. 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.

5.3. The performance security shall be denominated in the currency of the Contract, or in a freely convertible currency acceptable to the Purchaser, and shall be in one of the following forms:

a. A bank guarantee or Letter of credit issued by a Commercial bank located in the Purchaser's country approved by the Central Bank of the Purchase's or a foreign bank, but "confirmed" by a Commercial bank operating in purchaser country, acceptable to the Purchaser, in the format provided in the Bidding Documents (Section –V) or another format acceptable to the Purchaser; or

b. A cashier's or certified cheque. (Personal cheque or company cheque are not accepted as performance security.); or

c. Payment will be restricted to 90% of the value in presentation of bills, the balance 10% will be released after 60 days from the date of bill of lading, if no claims are intimated.

5.4. The performance security will be discharged by the Purchaser and returned to the Supplier not later than twenty-eight (28) days following the date of completion of

the Supplier's performance obligations under the Contract, including any warranty obligations, unless **specified otherwise in the SCC.**

6. Inspections and Tests

6.1. 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. The **SCC** and the Technical Specifications shall specify what inspections and tests the Purchaser requires and where they are to be conducted. The Purchaser shall notify the Supplier in writing, in a timely manner, of the identity of any representatives retained for these purposes.

a. 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.

b. 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.

c. Upon receipt of the Goods at place of final destination, the Purchaser's representative shall inspect the Goods or part of the Goods to ensure that they conform to the condition of the Contract.

6.2. Where the Supplier contests the validity of the rejection by the Purchaser or his representative, of any inspection as required by 6.1 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, within 30 calendar days after giving the notice by buyer, if the supplier fail to do so within the stipulated time buyer will draw the sample and, will be forwarded for analysis to NDQAL (National Drug Quality Assurance Laboratory) of Sri Lanka. If the item cannot be tested by the NDQAL 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.

7. Packing

7.1. 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.

7.2. 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, if any, **specified in the SCC**, Technical Specifications or Schedule of requirement, and in any subsequent instructions ordered by the Purchaser.

8. Delivery and Documents

8.1. Delivery of the Goods shall be made by the Supplier in accordance with the terms specified in the Schedule of Requirements. The details of shipping and/or other documents to be furnished by the Supplier are **specified in the SCC.**

8.2. For purposes of the Contract, "EXW," "FOB," "FCA," "CIF," "CIP," and other trade terms used to describe the obligations of the parties shall have the meanings assigned to them by the current edition of *Incoterms* published by the International Chamber of Commerce, Paris.

8.3. Documents to be submitted by the Supplier are **specified in the SCC.** *Incoterms* provides a set of international rules for the interpretation of the more commonly used trade terms.

9. Insurance

9.1. The Goods supplied under the Contract shall be fully insured in a freely convertible currency against loss or damage incidental to manufacture or acquisition, transportation, storage, and delivery in the manner **specified in the SCC.**

9.2. Where delivery of the Goods is required by the Purchaser on a CIF or CIP basis, the Supplier shall arrange and pay for cargo insurance, naming the Purchaser as beneficiary. Where delivery is on an FOB,C&F,CPT or FCA basis, insurance shall be the responsibility of the Purchaser.

10. Warranty

10.1. 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 two –third(2/3) of the residual shelf life at the time of receipt in Sri Lanka, unless otherwise specified in the SCC; 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.

10.2. The Purchaser shall have the right to make claims under the above warranty for three months after the Goods have been delivered to the final destination indicated in the Contract. 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.

10.3. In the event of a dispute by the Supplier with regard to defective Goods, 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.

10.4. If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 10.2 above, the Supplier fails to replace the defective Goods within the period specified in the SCC, 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 and by law. The Purchaser will also be entitled to claim for storage in respect of the defective Goods for the period following notification and deduct the sum from payments due to the Supplier under this Contract.

10.5. 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 fulfill its recall obligation promptly, the Purchaser will, at the Supplier's expense, carry out the recall.

11. Payment

11.1. The method and conditions of payment to be made to the Supplier under this Contract shall be specified in the SCC.

12. Prices

12.1. 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, with the exception of any price adjustments authorized in the SCC or in the Purchaser's request for bid validity extension, as the case may be.

13. Change Orders

13.1. The Purchaser may at any time, by a written order given to the Supplier pursuant to GCC Clause 26, 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

13.2. 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.

14. Contract Amendments

14.1. Subject to GCC Clause 13, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties.

15. Assignment

15.1. 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.

16. Delays in the Supplier's Performance

16.1. Delivery of the Goods and performance of Services shall be made by the Supplier in accordance with the time schedule prescribed by the Purchaser in the Schedule of Requirements.

16.2. If at any time during performance of the Contract, the Supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the Goods and performance of Services, the Supplier shall promptly notify the Purchaser in writing of the fact of the delay, its likely duration, and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without liquidated damages, in which case the extension shall be ratified by the parties by amendment of Contract.

16.3. Except as provided under GCC Clause 19, 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 17, unless an extension of time is agreed upon pursuant to GCC Clause 16.2 without the application of liquidated damages.

17. Liquidated Damages

17.1. Subject to GCC Clause 19, 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 Contract Price, as liquidated damages, a sum equivalent to the percentage specified in the SCC 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 percentage specified in the SCC. Once the maximum is reached, the Purchaser may consider termination of the Contract pursuant to GCC Clause 18.

18. Termination for Default

18.1. The Purchaser, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate this 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 16; or

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

(c) if the Supplier fails to provide any registration or other certificates in respect of the Goods within the time specified in the Special Conditions.

(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 noncompetitive 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.

18.2. In the event the Purchaser terminates the Contract in whole or in part, pursuant to GCC Clause 18.1, the Purchaser may procure from a third party, 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.

19. Force Majeure

19.1. Notwithstanding the provisions of GCC Clauses 16, 17, and 18, the Supplier shall not be liable for forfeiture of its performance security, 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.

19.2. 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.

19.3. 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.

20. Termination for Insolvency

20.1. 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.

21. Termination for Convenience

21.1. The Purchaser, by 30 days prior written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time without cause. The notice of termination shall specify, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.

21.2. 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.

22. Settlement of Disputes

22.1. 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.

22.2. 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.

2.2.2.1. 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.

2.2.2.2. Arbitration proceedings shall be conducted in accordance with the rules of procedure **specified in the SCC.**

22.3. 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 the Supplier.

23. Limitation of Liability

23.1. Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 4,

(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 Contract Price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.

24. Governing Language

24.1. The Contract shall be written in the language specified in the SCC. Subject to GCC Clause 25, the version of the Contract written in the specified language shall govern its interpretation. All correspondence and other documents pertaining to the Contract that are exchanged by the parties shall be written in the same language.

25. Applicable Law

25.1. The Contract shall be interpreted in accordance with the laws of the Purchaser's country, unless otherwise **specified in the SCC.**

26. Notices

26.1. Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing or by facsimile and confirmed in writing to the other party's address specified in the SCC.

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

SECTION IV. SPECIAL CONDITIONS OF CONTRACT

Special Conditions of Contract

The following Special Conditions of Contract shall supplement the General Conditions of Contract. Whenever there is a conflict, the provisions herein shall prevail over those in the General Conditions of Contract. The corresponding clause number of the GCC is indicated in parentheses.	
1.Definitions (GCC Clause 1)	
GCC1.1 (f)	The Purchaser is*:* State Pharmaceutical Manufacturing Corporation
GCC1.1(g)	The Purchaser's country is: Democratic Socialist Republic of Sri Lanka
2. Application (GCC Clause 2)	
GCC 2	*"There are no Special Conditions of Contract applicable to GCC 2."*
3.Standards (GCC Clause 3)	
GCC 3	*"There are no Special Conditions of Contract applicable to GCC 3."*
4. Patent Rights (GCC Clause 4)	
GCC 4	*"There are no Special Conditions of Contract applicable to GCC 4."*
5.Performance Security (GCC Clause 5)	
GCC 5	The successful bidder shall within 28 days from the notification of award submit an unconditional Performance security upto10% of the total value of award. Failure to comply with this request shall constitute sufficient grounds for the SPMC to cancel such award and forfeit the bid security. Letters forwarding the performance security should be addressed to the Chairman – State Pharmaceuticals Manufacturing Corporation No. 11, Sir John Kotalawala Mw, Kandawala Estate, Ratmalana. The validity of the performance security Shall be ninety (90) calendar days from the date of goods received by SPMC or as indicated in the indent. whichever is higher. Claims on the performance security will be made by us in the very first instance the supplier fails to comply with the terms and conditions of contract and/or L/C.
6. Inspection and Tests (GCC Clause 6)	
GCC6.1 (b)	We reserve the right to nominate independent competent authorities for the issue of pre-shipment Inspection certificate (Certificate of quality, quantity & loading). In such event, the cost of such certificate must be borne by the supplier

7. Packing (GCC Clause 7)	
GCC7.1	**PACKING AND STORAGE CONDITIONS** (i) Pack size offered should conform to SPMC requirements. Bids for alternate pack sizes may be rejected. Export-worthy packing which will prevent damage in transit should be used. Details of nature of packing should be given. (ii) Packing of all items should be suitable for storage and use under tropical conditions. Final export packing should indicate the required storage temperature for goods which require refrigeration / cool room / freezer storage enable the cargo handling staff at the Port of Colombo or transshipment Port to arrange proper storage for such goods immediately on arrival. (iii) Containers and closures used should be of such quality so as not to react with the contents while in storage under tropical conditions. (iv) Final export packing should be in seaworthy strong cases or cartons, details of shipping marks which will be provided with order should be stenciled. Bag cargo should be palletized and shrink wrapped. (v) Humidity in Sri Lanka is usually between 75% and 100% and temperature is in the range 50°F to 91°F(15°C to 35°C).
GCC7.2	**LABELLING & MARKING** (A) All labels should be printed in English language and should carry out at least the following information. (a) The international nonproprietary name (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; (b) The applicable pharmacopoeia standard; (c) Content per Pack; (d) Indent no. (e) Recommended storage condition. (f) Batch number. (g) Container no. (h) Date of manufacture. (in clear language, not code);

	(i) Date of expiry. (in clear language, not code); (j) Name and address of the manufacturer. (k) Name and address of the supplier, if supplier is not the manufacturer. (l) Marks and numbers (shipping marks.) (m) Any additional cautionary statement
8. Delivery and Documents (GCC Clause 8)	
GCC 8.1 ITB 8.3	• All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation (CSC) or those chartered by CSC, Shipments on other vessels will be permitted in instances where vessels of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation or their Authorized agent in the suppliers country. • SPMC may nominate independent competent authorities for issue of shipment inspection certificate (Certificate of quality, Quantity and loading) cost of such certificate should be borne by the supplier. • All items should be shipped to the destination and strictly conform to the delivery dates as per schedule of requirement • Delivery of all goods should be within the period of validity of the Letter of Credit. Except in exceptional circumstances no extensions will be granted. Cost of such extension if any would be borne by the supplier. ***For Goods supplied from abroad:*** Upon shipment, the Supplier shall notify the Purchaser and the insurance company in writing the full details of the shipment including Contract number, description of the Goods, quantity, date and place of shipment, mode of transportation, and estimated date of arrival at place of destination. In the event of Goods sent by airfreight, the Supplier shall notify the Purchaser a minimum of forty-eight (48) hours ahead of dispatch, the name of the carrier, the flight number, the expected time of arrival, and the waybill number. The Supplier shall fax and then send by courier the following documents to the Purchaser, with a copy to the insurance company:

	(i) three originals and two copies of the Supplier's invoice, showing Purchaser as *[enter correct description of Purchaser for customs purposes];* the Contract number, Indent number, Goods description, quantity, unit price, and total amount. Invoices must be signed in original, stamped, or sealed with the company stamp/seal; **Break-up value** of CPT/CFR (Into FOB and Freight) should be indicated in in invoice. (ii) one original and two copies of the negotiable, clean, on-board through bill of lading marked "freight prepaid" and showing Purchaser as *[enter correct name of Purchaser for customs purposes]* and Notify Party as stated in the Contract, with delivery through to final destination as per the Schedule of Requirements and two copies of non-negotiable bill of lading, or three copies of railway consignment note, road consignment note, truck or air waybill, or multimodal transport document, marked "freight prepaid" and showing delivery through to final destination as per the Schedule of Requirements; (iii) four copies of the detail packing list identifying contents of each package; (iv) Two originals of Certificate of analysis for every Batch of the consignment must include the name of the manufacturer and it must be authorized by a Quality Controller or Quality Assurances Manager who is responsible for, and qualified to analyze material. (v) copy of the Insurance Certificate, showing the Purchaser as the beneficiary; (If payment term CIF or CIP) (vi) one original of the manufacturer's or Supplier's Warranty Certificate covering all items supplied; (vii) one original of the Supplier's Certificate of Origin covering all items supplied; (viii) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required); (ix) any other procurement-specific documents required for delivery/payment purposes.

	For Goods from within the Purchaser's country: Upon or before delivery of the Goods, the Supplier shall notify the Purchaser in writing and deliver the following documents to the Purchaser: (i) two originals and two copies of the Supplier's invoice, showing Purchaser, the Contract number, SPMC Purchase Order 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) two copies of delivery note, railway consignment note, road consignment note, truck or air waybill, or multimodal transport document showing Purchaser as *[enter correct name of Purchaser for customs purposes]* and delivery through to final destination as stated in the Contract; (iii) copy of the Insurance Certificate, showing the Purchaser as the beneficiary; (iv) four copies of the packing list identifying contents of each package; (v) one original of the 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) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required) (viii) other procurement-specific documents required for delivery/payment purposes. Demurrage charges, if any which become payable due to supplier's failure to comply with above requirements will be claimed from supplier.
GCC 8.2	The Applicable Incoterms edition is: Incoterms 2010
9. Insurance (GCC Clause 9)	
GCC 9	The insurance shall be in an amount equal to 110 percent of the CIF or CIP value of the Goods from "warehouse" to "warehouse" on "All Risks" basis, including war risks and strikes (**only if contract placed on CIF or CIP basis**).

10. Warranty(GCC Clause 10)	
GCC 10	**FREE REPLACEMENT** SPMC reserves the right to call for the replacement or reimbursement in the event of * Short packing / supply * Loss damage or deterioration of goods supplied (within shelf life) * Packs which cannot be identified due to labels falling off. * Goods supplied fails to perform or meet requirements of the specification to the satisfaction of SPMC In the event of the quality problem, representative batch samples would be tested by SPMC or its authorized personnel at the National Drug Quality Assurance Laboratory. Samples from the available batch will be retained by the SPMC and the balance will be destroyed by SPMC in the presence of the Local Agent and a certificate of destruction issued by SPMC. The suppliers should however, agree to reimburse us by the landed cost of the total quantity rejected.(for which a certificate of destruction will be provided)
GCC 10.4	The period for the replacement of defective good is : 90 Days
11. Payment (GCC Clause 11)	
GCC 11	Payment terms will be by confirmed irrevocable Letter of Credit at sight, unless otherwise agreed. Suppliers should strictly conform to their terms and condition of our indents and Letter of Credit and should not request amendments. If confirmed L/C required, confirmation charges should be on bidders accounts. • Orders may have to be cancelled and performance security (if applicable) forfeited if suppliers request amendments / extensions to letter of credit. • In particular, please note the following clauses which will be incorporated in our latter of credit and which clauses will not be deleted by us. A certificate from shipping agents in port of shipment that cargo and/or interests are carried by a mechanically self-propelled seaworthy vessel classed under Lloyd's Register of Shipping as 100A1(or equivalent classification in other recognized registers), provided such vessels are not over 15 years of age, or over 15 years but not over 25 years of age, and have an established schedule to load and a regular pattern of training on an advertised schedule to load and unload at specific ports.

	All bank charges incurred outside Sri Lanka shall be borne by the supplier. Payment to local suppliers will be made after 30 days from the date of delivery. <u>BANK CHARGES</u> i. All bank charges incurred outside Sri Lanka shall be to the beneficiary (s) accounts. Delivery should be made within validity of L/C and extension will be granted only in exceptional circumstances and costs of such extensions will be to the account of beneficiary. ii. NOMINATION OF BANK Letter of Credit will be advised through the correspondent bank of our bankers in the successful bidder's country. However, if the bidder wishes to negotiate documents through any particular bank of their choice such details should be indicated in their offer.
12. Price (GCC Clause 12)	
GCC 12	Prices shall be fixed and firm for the duration of the Contract.
13. Change orders (GCC Clause 13)	
GCC 13	*"There are no Special Conditions of Contract applicable to GCC 13."*
14. Contract Amendments (GCC Clause 14)	
GCC 14	*"There are no Special Conditions of Contract applicable to GCC 14."*
15. Assignment (GCC Clause 15)	
GCC 15	*"There are no Special Conditions of Contract applicable to GCC 15."*
16. Delay in the Supplier's Performance (GCC Clause 16)	
GCC 16	*"There are no Special Conditions of Contract applicable to GCC 16."*
17. Liquidated Damages (GCC Clause 17)	
GCC 17	Delivery of goods shall not be later than the time specified in schedule of Requirement herein. Failure to deliver within the time specified and in the absence of force majeure there shall be deducted **one percent (1%) of contract value** as liquidated damages (not as a penalty) for each seven days of delay or part thereof commencing from the last date of the due date of delivery (mention in LC or

	Purchase order) of such undelivered item of goods. The amount of liquidated damages shall however be subject to a maximum limitation of ten (10 percent of the unit delivered price for each item so delayed). Delays in excess of **seventy (70) days** from date of due delivery will be cause for termination of contract and forfeiture of the performance security after written notice is given to the supplier.
18. Termination for Default (GCC Clause 18)	
GCC 18	*"There are no Special Conditions of Contract applicable to GCC 18."*
19. Force Majeure (GCC Clause 19)	
GCC 19	*"There are no Special Conditions of Contract applicable to GCC 19."*
20. Termination for Insolvency (GCC Clause 20)	
GCC 20	*"There are no Special Conditions of Contract applicable to GCC 20."*
21. Termination for Convenience (GCC Clause 21)	
GCC 21	*"There are no Special Conditions of Contract applicable to GCC 21."*
22. Settlement of Disputes (GCC Clause 22)	
GCC 22	The dispute resolution mechanism to be applied pursuant to GCC Sub-Clause 22.2.2 shall be as follows: ***(a) Contracts with foreign Supplier:*** All disputes arising out of or in connection with this Contract shall be finally settled by arbitration in accordance with the arbitration rules of the Singapore International Arbitration Center ("SIAC"). The arbitral tribunal shall consist of a sole arbitrator, to be appointed by the Chairman of the SIAC. The place of arbitration shall be Singapore. Any award by the arbitration tribunal shall be final and binding upon the parties. ***(b) Contracts with Supplier national of the Purchaser's country:*** Any dispute that may arise between the SPMC and the Supplier arising out of or in connection with this Contract shall be finally resolved by arbitration in terms of the Arbitration Act No. 11 of 1995. A party seeking Arbitration shall nominate an Arbitrator in the Notice of Arbitration. The other party may either accept or nominate another Arbitrator within six weeks of the said Notice. The Arbitrator nominated in the said Notice shall be the sole Arbitrator if the other party either accept such nomination or fails to respond to the said Notice within six weeks. The Arbitration panel shall consist of three Arbitrators if the other party nominates another arbitrator in the

	manner aforesaid and the chairman of the Arbitration panel shall be jointly appointed by the two Arbitrators appointed by each Party within 12 weeks of the said Notice. The place/seat of Arbitration shall be at Colombo, Sri Lanka. The language of the Arbitration shall be English. The evidence at the Arbitration shall be adduced by way of affidavits the Arbitrator(s) decide otherwise.
23. **Limitation of Liability (GCC Clause 23)**	
GCC 23	*"There are no Special Conditions of Contract applicable to GCC 23."*
24. **Governing Language (GCC Clause 24)**	
GCC 24	Governing language is English
25. **Applicable Law (GCC Clause 25)**	
GCC 25	The Contract shall be interpreted in accordance with the laws of the: Democratic Socialist Republic of Sri Lanka
26. Notices (GCC Clause 26)	
GCC 26	*"There are no Special Conditions of Contract applicable to GCC 26."*

SECTION V. SAMPLE FORMS

1. BID FORM

Date: …….

Chairman,
Cabinet Appointed / Ministry/Corporation Procurement committee
……
……

BID FOR THE SUPPLY OF [*insert : Name of the Item]*

ITEM NO: *[insert : Item Number mentioned in schedule of requirement]*

IFB NUMBER.: [*insert]*

1.I/We, the undersigned, having read and fully acquainted myself/ourselves with the contents of the conditions of Bidding document and Contract and schedule of requirement pertaining to the above Bid, hereby undertake to supply the goods referred to therein, in accordance with the aforesaid instructions, terms and conditions as per price quoted in the attached statement of compliance.

2. I/We confirm that this offer shall be open for acceptance until ……. and that it will not be withdrawn of revoked prior to that date.

3. I/We attach hereto the following documents as part of my/our bid:-

(1) Dully filled Statement of compliance
(2) Original form of bid security
(3) Duly filled Manufacturer Authorization Form
(4) Power of Attorney or Letter of Authorization
(5) Any other documents accordance with ITB 9 (give details)

4. I/We understand that you are not bound to accept the lowest bid and that you reserve the right to reject any or all bids or to accept any part of a bid without assigning any reasons therefore.

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

6. 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.

7. 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

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**]*

2. MANUFACTURER'S AUTHORIZATION FORM

[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]*
No.: *[insert bid identification No.]*

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 10 of the general conditions of contract & special 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 or position]*

Duly authorized to sign this Authorization on behalf of: *[insert complete name of Bidder]*

Dated on _____ day of _____, _____ *[insert date of signing]*

3. STATEMENT OF COMPLIANCE

SUPPLY OF [*Insert: Name of the Item*]

i) Duly filled statement of compliance should be sent with the Bid document.
ii) Specify whether offered specifications comply with required specifications.
iii) Bid may be considered as invalid if this statement of compliance is not duly filled.
iv) Bidders are instructed to send a covering letter in their company letter head with the official seal with the duly filled statement of compliance

	Description and Specification of <u>REQUIRED</u> Material	**Description and Specification of <u>OFFERED</u> Material**
1.	Item: (As Per the Schedule of requirement)	
2.	Quantity (As Per the Schedule of requirement)	
3.	Delivery schedule (As Per the Schedule of requirement)	
4.	Packaging (As Per the Schedule of requirement)	
5.	Mode of payment	
6.	Mode of transport (Sea/Air) Port of Shipment	
7.	**C&F price per kg** **(Should quote only C&F price)**	
8.	Local Agent's commission	
9.	Total cost	
10.	Total Cost in Words	
11.	<u>Shelf life</u> As requested in the schedule of requirement	
12.	Country of origin	
13.	Validity of offer	
14.	State whether sample is included or not	

	Description and Specification of <u>REQUIRED</u> Material	**Description and Specification of <u>OFFERED</u> Material**
15.	Certificate of analysis must include above specifications.	
16.	Name & address of the manufacturer of the material	
	Telephone:	
	Fax :	
	e-mail:	
17.	Name & address of the Bidder (foreign)	
	Telephone:	
	Fax :	
	e-mail:	
18.	Name & address of the local agent (If applicable)	
	Telephone:	
	Fax :	
	e-mail:	
19.	Bid security submitted/not submitted & value	
20.	Signature and official seal of the Bidder	

4. FORMAT FOR BID SECURITY (BANK GUARANTEE)

[***This bank guarantee form shall be filled in accordance with the instructions indicated in brackets***]

_____[*insert issuing agency's name , and address of issuing branch or office*]
_____

Beneficiary_____*[insert(by PE) name and address of Purchaser]*
Date: …….. *(insert (by issuing agency) date)*
BID GUARNTEE NO. *:……[insert (by issuing agency) number]*
We have been informed that …… *[insert (by issuing agency] name of the Bidder; if a joint venture, list complete legal names of partners*) (hereinafter called "the Bidder") has submitted to you its bid dated ……. .[insert (by issuing agency) date] (hereinafter called "the Bid") for the execution/ supply [select appropriately] of [insert name of contract] under invitation for bids No._____[insert IFB number] ("the IFB").
Furthermore, we understand that, according to your conditions, bids must be supported by a bid guarantee.

At the request of the bidder, we _____[insert name of issuing agency] hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of _____[insert amount in figures] _____[insert amount in words]) upon receipt by us of your first demand in writing accompanied by a written statement stating that the Bidder is in breach of its obligation(s) under the bid conditions, because the bidder:

a) has withdrawn its Bid during the period of bid validity specified; or

b) does not accept the correction of errors in accordance with the instructions to bidders (hereinafter "the ITB") of the IFB; or

c) having been notified of the acceptance of its Bid by the purchaser during the period of bid validity, (i) fails or refuses to execute the Contract Form, if required, or (ii) fails or refuses to furnish the performance security, in accordance with the ITB.

This guarantee shall expire: (a) if the bidder is the successful bidder, upon our receipt of copies of the signed by the bidder and of the performance security issued to you by the bidder; or (b) if the bidder is not the successful bidder, upon the earlier of (i) our receipt of a copy of your notification to the Bidder that the bidder was unsuccessful, otherwise it will remain in force up to _____ *(insert date)*

Consequently, any demand for payment under this guarantee must be received by us at the office on or before that date. _____

[signature(s) of authorized representative(s)]

5. FORMAT FOR PERFORMANCE BANK GUARANTEE

_____[Issuing Agency's Name, and Address of Issuing Branch or office] _____

Beneficiary: ______[Name and Address of Employer]_____

Date: _____

PERFORMANCE GUARANTEE NO.: _____

We have been informed that _____[*name of contractor/ Supplier*] (hereinafter called "the Contractor") has entered into Contract No._____ *[reference number of the contract]* dated _____with you, for the _____ *[insert "construction" / "Supply"]* of _____*[name of contract and brief description of* works] (hereinafter called "the contract").

Furthermore, we understand that, according to the conditions of the contract, a performance guarantee is required.

At the request of the Contractor, we _____[*name of Agency*] hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of _____*[amount in figures]* (_____) *[amount in words]*, such sum being payable in the types and proportions of currencies in which the contract Price is payable, upon receipt by us of your first demand in writing accompanied by a written statement stating that the contractor is in breach of its obligation(s) under the contract, without your needing to prove or to show grounds for your demand or the sum specified therein.

This guarantee shall expire, no later that the…… day of ……., 20… *[insert date, 28 days beyond the scheduled contract completion date]* and any demand for payment under it must be received by us at this office on or before that date.

_____
[signature(s)]

6. 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 in the sum of *[insert: **contract price in words and figures**]* (hereinafter called "the Contract Price").

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) Special Conditions of Contract

   (c) General Conditions of Contract

   (d) Technical Requirements (including Technical Specification)

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

   (f) The Purchaser's Notification of Award

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.

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"

7. SUPPLIER APPROVAL QUESTIONNAIRE

The purpose of this questionnaire is to allow us to identify a number of suitably qualified manufacturers and suppliers for Pharmaceutical Active Ingredients and Excipients, who will be invited to submit tenders for next three years period.

Questionnaire Layout

This form contains of four parts:

Part I Business Information
Part II Manufacturing Information
Part III Quality Information
Part IV Product Information

All information requested should be provided in the order and format of the parts.

Completed questionnaire may be sent through the post under registered cover or may personally be deposited in the box kept for this purpose on the ground floor at the State Pharmaceuticals Manufacturing Corporation, No 11, Sir John Kotelawala Mawatha, Kandawala Estate, Ratmalana, Sri Lanka.

- Only information provided as a direct response to the questionnaire will be evaluated.
- Marketing material should not be included.
- Supplementary documentation may be attached to the questionnaire where applicants have been directed to do so and such materials must be marked with the name of the organization and the question to which it relates.
- All questions must be answered.
- Please answer the questions specifically for your relevant firm not for the group if you are part of a group of Firms.
- Should you decide that you do not wish to continue with this application, please advise the procurement committee of your decision in writing at the earliest opportunity.
- The information you give will be treated as confidential.

Ensure that the completed questionnaire, together with all requested supporting documents, is returned in time to arrive by 26th March 2024. **(Closing date). Questionnaires received after this date will not be considered.**

I. BUSINESS INFORMATION.

1. Name of company: _____

   Year established: _____

   Form of company:
   - ☐ Individual
   - ☐ Partnership
   - ☐ Corporation
   - ☐ Other (specify)

   Legal status: _____

   Trade register number: _____

   VAT number: _____

   License Number *(attach copy)*: _____

2. Address: _____

   Country: _____

   Telephone: _____ Telefax: _____

   Telex: _____ E-mail: _____

Please attach the company organizational chart

3. Type of activity carried out by the company

☐ Manufacturer	☐ Wholesaler
☐ Branded products	☐ Branded products
☐ Generic products	☐ Generic products
☐ Medical supplies	☐ Medical supplies
☐ API	☐ Excipient
☐ Laboratory reagents	☐ Laboratory reagents
☐ Other products *(specify below)*	☐ Other products *(specify below)*

Indicate % of annual turnover:

Pharmaceutical formulations:	_____%
Bulk drugs:	_____%
Medical Supplies:	_____%
Excipient	_____%

☐ Products manufactured for export
☐ Sold only to the local market
☐ Both

4. Names and addresses of international pharmaceutical companies, parent companies and/or subsidiaries and associated companies with whom there is collaboration or joint venture, if any:

Company	Address
_____	_____
_____	_____
_____	_____

5. Employees:

Total: _____
Management: _____
R&D _____
Sales _____
Administrative _____
Others *(specify):* _____

6. Capital value of the company *(specify currency)*
   (a) Authorized capital: _____
   (b) Paid up capital: _____
   (c) Administration: _____

7. Annual sales turnover in the previous three years. Split export and domestic sales. *(specify currency)*

Annual turnover	Domestic sales	Exports	Year

II. MANUFACTURING INFORMATION.

1. Total number of Items manufactured: _____
   (provide list of manufactured products)
2. Are all manufacturing operations (processing, packaging, labeling) carried out internally?

   ☐ YES ☐ NO

   If "No," attach a list of pharmaceuticals and/or raw materials/ Excipients manufactured by other companies and marketed by you. Please give the names of the companies, for each item.

	Product	Manufacturer	Address
(1)			
(2)			
(3)			

3. Provide details if pharmaceutical products and/or raw materials/ Excipients manufactured by your company are exported to other countries

Pharmaceutical product/raw material	Country	Generic Name	Trade Name
(1)			
(2)			
(3)			

4. Does your company have GMP certification?

   ☐ Yes *(attach a copy of the GMP certificate if any)*
   Certified by: _____

   ☐ No

Indicate if your company has other types of certification

- ☐ ISO Type of ISO certification: _____
- ☐ WHO Certification Scheme
- ☐ Others *(specify)* _____

Attach Certificates of Good Manufacturing Practices (GMP, ISO or Certificates of Pharmaceutical Products according to WHO. Certification Scheme covering each item you propose to export.

5. Does your Government carry out inspections and controls on the production of drugs in your country?

   ☐YES ☐NO

   If "Yes", give date of last inspection: _____

6. Has your company been inspected by other governments, organizations or clients?

   Inspected by Year Outcome

7. Date, number and expiry date of current business license or permit.

   Date: _____

   Number: _____

   Expiry Date: _____

8. Date, number and expiry date of manufacturing license or permit.

   Date: _____

   Number: _____

   Expiry Date: _____

9. If you are a Traderer /wholesaler, the following information should be obtained from the manufacturers of product you wish to offer.

   A. Give full details on the manufacturer (company name and address), with product lists and brochures of the manufacturing plants, laboratories etc.

   Manufacturer: _____

   Address: _____

   B. Are the products in the product list produced routinely by the company?

   ☐ YES ☐ NO

   C. Or only occasionally on request?

   ☐ YES ☐ NO

D. Number of specialized personnel involved in the manufacture of pharmaceuticals *(exclude administrative personnel).*

Pharmacists: _____

Chemists: _____

Others: _____

10. A. Are the products manufactured by your company, manufactured under contract by other companies or repackaged?

- ☐ Manufactured
- ☐ Repackaged
- ☐ Manufactured under contract

B. If any products are manufactured under contract, attach a list of such products with the name and address of the manufacturer for each product.

	Product	Manufacturer	Address
(1)			
(2)			
(3)			

C. If any products are repackaged, attach a list of such products with the name and address of the manufacturer for each product.

	Product	Manufacturer	Address
(1)			
(2)			
(3)			

11. Do other companies package any of the products you manufacture?

☐ YES ☐ NO

If any products are repackaged, attach a list of such products with the name and address of the manufacturer for each product.

	Product	Manufacturer	Address
(1)			
(2)			
(3)			

Provide detailed information on the quality assurance procedures followed.

_____

_____

_____

_____

_____

12. Do you manufacture beta-lactam antibiotics?

☐ YES ☐ NO

If "Yes," are these production facilities in a separate building?

☐ YES ☐ NO

13 Production site

Are the production premises located in the same place as the main office?

☐ Yes ☐ No

If not, state address of the production premises: _____

Address: _____

_____

_____

If there are >1 production site, give description of production site as follows:

Production site

Address

No. Of products

Production capacity

Quality of in process water

List the products from the different production sites:

Production site Products

III. QUALITY INFORMATION

1. Do you maintain your own quality control laboratory?

   ☐ YES ☐ NO

2. Number of specialized personnel working in your quality control laboratory (excluding administrative personnel).

   Pharmacists: _____

   Chemists: _____

   Others: _____

3. List names and addresses of quality control laboratories used in addition to or in lieu of your own laboratory.

   _____

   _____

4. Are all raw materials completely tested prior to use or is a Certificate of Analysis accepted?

   ☐ YES ☐ NO ☐ Certificate of Analysis

5. Quality standards

   ☐ BP Edition ☐ USP Edition ☐ EP Edition ☐ IP Edition

   ☐ JP Edition ☐ CP Edition ☐ Other:

   Are all recommended tests carried out?

   ☐ YES ☐ NO

   If "No," state reason why not

   _____

   Are additional tests carried out?

   ☐ YES ☐ NO

   If "No," state reason why not

   _____

6. Are control samples of each batch retained?

   ☐ YES ☐ NO

7. Do you have written cleaning procedures?
   ☐ YES ☐ NO

8. Do you have a written recall procedure?
   ☐ YES ☐ NO

9. Do you have a written procedure on how to deal with complaints?
   ☐ YES ☐ NO

10. Name and title of the authorized person (s) responsible for batch release:
    Name: _____
    Title: _____
    Experience in pharmaceuticals: _____ years

    (of change – should inform)

11. Name and qualification of the head of the Quality Control department:
    Name: _____
    Qualification: _____
    Experience in pharmaceuticals: _____ years

    (If change – should notify us)

12. Indicate if you perform quality tests conducted routinely:
    ☐ active starting materials
    ☐ non-active starting materials
    ☐ packaging materials
    ☐ intermediate products
    ☐ bulk products
    ☐ finished products

13. Are all quality control tests performed internally?
    ☐ YES ☐ NO
    If "No," list tests performed by external laboratories:

Tests	Laboratories	Address
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

14. Explain process of approving sources for starting materials and describe basis for approving specifications of starting materials.

_____
_____
_____
_____

15. Do you conduct tests on each container of the active starting material?

☐ YES ☐ NO

If not, explain your way of sampling: _____

_____

16. Do you test each container of non-active starting materials?

☐ YES ☐ NO

If "No," describe method of sampling: _____

_____

17. Are you willing to reveal the sources of starting material? (Information will be deemed confidential)

☐ YES ☐ NO

18. Are stability tests routinely conducted for every product?

☐ YES c ☐ NO

If "No," state reason why not: _____

_____

19. For each batch, what are the check procedures that are routinely done:

- ☐ Batch numbers and control numbers of each component
- ☐ Weighed quantities double checked and signed off for each component
- ☐ Acceptance record of each component
- ☐ Date and time of each stage of production
- ☐ Identification of equipment used
- ☐ Name of persons in charge at each stage
- ☐ In-process control results
- ☐ Environment control results
- ☐ Remarks on production incidents
- ☐ Comments on not following the master formula
- ☐ Yield and reconciliation
- ☐ Packaging material batch numbers
- ☐ Line clearance sign off
- ☐ Result of QC of end product
- ☐ Inspection checks and test results, dates and signatures of inspecting

20. Do you keep samples of each batch?

☐ YES ☐ NO

Indicate how long do you keep the samples: _____ years

21. Are these kept in the original containers?

☐ YES ☐ NO

22. Do you carry out inspections or quality audits of your own suppliers?

☐ YES ☐ NO

If "Yes," describe audits in detail:

_____

_____

_____

_____

23. Describe your storage facilities:

_____

_____

_____

IV. Product Information (Please fill up one form for each product)

1. Active Pharmaceutical Ingredient(s) _____
_____
_____

Indicate if product has any of the following:

☐ Certificate of Suitability to the European Pharmacopoeia (CEP)
Certificate No.: _____
☐ The CEP is in our possession (including annex if any)

☐ Drug Master File (DMF)
registered in *(country)*: _____
registration no.: _____
☐ The full or open part of the DMF is in our possession
☐ The full or open part of the DMF is in possession of the manufacturer
Manufacturer: _____
Country: _____

2. Regulatory Status in Country of Origin

☐ Product registered in country of origin and routinely manufactured and marketed
License no: _____ year issued: _____

☐ Product registered in the country of origin but not currently marketed
License no: _____ year issued: _____

☐ Product registered for export only
License no: _____ year issued: _____

☐ Product not registered

3. Regulatory Status in Other Countries
List other countries where the product is registered and currently marketed:

Product	Country	Trade Name
_____	_____	_____
_____	_____	_____
_____	_____	_____

4. Validation

Are all your production processes validated?

☐ Yes ☐ No

5. Do you use an approved manufacturing formula and processing instructions?

☐ Yes ☐ No

6. Finished Product Specification

☐ BP ☐ USP Edition ☐ IP

☐ JP ☐ Any other

Attach a copy of the finished product specifications

Are you willing to provide necessary information (analytical methods) for the tests to be replicated by another control laboratory?

☐ Yes ☐ No

7. Limits in % for the assay in active ingredient(s):

☐ 95-105% ☐ 90-110 %

☐ Other: _____

Additional specifications to those in the pharmacopoeia:

_____

_____

Attach a copy of the model certificate of analysis for batch release

8. Stability

Stability testing data available: ☐ Yes ☐ No

Type and conditions of satisfactory testing (without significant change):

☐ accelerated testing

☐ 40°/75% RH/6 months

☐ other:

☐ in the same packaging as marketed

☐ in another packaging:

☐ real time testing

Temperature: ☐ ambient ☐ 25°C ☐ 30°C ☐ other: __
Relative humidity: ☐ 45% ☐ 60% ☐ 70%
☐ not controlled ☐ other: _____
Period of time: ☐ 1 year ☐ 2 years ☐ 3 years ☐ other: __
☐ in the same packaging as marketed
☐ in another packaging: _____

9. Label and Insert Information

Shelf life: ☐ 2 years ☐ 3 years ☐ 4 years
☐ 5 years ☐ other: _____

Storage conditions (e.g. Store below 30°- Protect from light):

_____

_____

Package insert: ☐ Yes ☐ No

Attach a copy of the label and package insert

CERTIFICATION

I, the undersigned (full name of the person responsible)

Name _____

Designation _____

Hereby declare that all the information given above is true, and I take the full responsibility for all consequences that might arise from false or erroneous information. If required, I will cooperate with any official of the State Pharmaceuticals Manufacturing Corporation of Sri Lanka in making personal inspection of manufacturing facilities and records.

Name _____
Designation _____
Signature _____
Date _____

Following documents should be send along with the Manufacture/supplier Questionnaire

1 Copy of manufacture license
2 copy of total number of items manufactured
3 Copy of valid GMP certificate/s
4 Copy of Business license or Permit
5 Copy of Manufacturing license
6 Copy of other certifications if (ISO, WHO etc)
7 Under the Product information Page 12 of 15

1 submit the Copy of the all necessary documents (drug master file, CEP-certification of suitability to the European pharmacopoeia

2 Copy of regulatory status product registration license etc

3 Regulatory status in other country

SECTION VI. SCHEDULE OF REQUIREMENTS

BID REF. NO. : SPMC/01/2024 **ITEM SCHEDULE I**

ISSUED FROM : 15.02.2024

CLOSING DATE & TIME : 26TH MARCH 2024 at 10.00 HOURS SRI LANKA TIME

ITEM NO.	DESCRIPTION OF ITEM WITH SPECIFICATIONS	PACK SIZE PREFERRED	QUANTITY REQUIRED	DELIVERY REQUIRED IN COLOMBO SRI LANKA	APPRX. VALUE OF BID SECURITY
1	**Amoxicillin Trihydrate BP 2020 (Compacted) (By Enzymatic Process)** Specifications : "Compacted Powder" Yellow particle free White and odourless powder. free from foreign matters. Tapped Density : 0.75 - 0.85g/cm^3 **Particle Size Distribution:** Retain on 20 mesh - 0 - 3% 20 - 80 mesh - (70% - 90%) 80 - 200 mesh - (5% - 20%) Pass through 200 mesh - (4% - 10%)	25kg nett in air-tight, strong, well - closed, Export Seaworthy HDPE drums with handles. Standard information label should be pasted inside top of the drum and indicate only marks and numbers on outside of drum. Diameter of the drum mouth - Approx. 35cm Height of the drum - Approx. 45cm Shape of the drum - Cylindrical with the plastic lid and handles. Each and every drum should be wrapped with polythene.	**27,000kg**	**9,000 kg - May 2024 to SPMC** **9,000 kg - July 2024 to SPMC** **9,000 kg - August 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs.5,000,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs.2,500,000.00** equivalent in USD as a Cash Deposit.
2	**Atorvastatin Calcium IP** Specifications : "Very fine Powder"	25kg. nett in air-tight, light resistant, strong, well closed, seaworthy fiber or plastic drums. Each and every drum should be wrapped with polythene.	**1,000kg**	**1,000 kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs.500,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 250,000.00** equivalent in USD as a Cash Deposit.
3	**Benzhexol Hydrochloride BP 2020** (Trihexyphenidyl Hydrochloride BP 2020) Specifications : "Crystalline Powder "	25 kg. nett in strong, air -tight, well-closed, fiber or plastic drums. Each and every drum should be wrapped with polythene film.	**75kg**	**75 kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 30,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs.15,000.00** equivalent in USD as a Cash Deposit.

2……../-

CLOSING DATE & TIME : 26TH MARCH 2024 at 10.00 HOURS SRI LANKA TIME

ITEM NO.	DESCRIPTION OF ITEM WITH SPECIFICATIONS	PACK SIZE PREFERRED	QUANTITY REQUIRED	DELIVERY REQUIRED IN COLOMBO SRI LANKA	APPRX. VALUE OF BID SECURITY
4	**Carbamazepine BP 2020** Particle size Distribution **Mesh size** **% Max passes through** Pass through 20 mesh 90% - 100% Pass through 40 mesh 20% - 60% Pass through 200 mesh 0% - 10%	25 kg. nett in air -tight, strong, well-closed, fiber or plastic drums. Each and every drum should be wrapped with polythene.	**2,000kg**	**2,000 kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs. 600,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 300,000.00** equivalent in USD as a Cash Deposit.
5	**Cetirizine Dihydrochloride BP 2020** Specifications : Fine Powder Pass through 80 mesh -N.L.T. - 95% Pass through 120 mesh -N.M.T. - 40%	25kg. Nett in air-tight, well closed, moisture proof container. Protect from light. Each and every drum should be wrapped with polythene.	**300kg**	**300 kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 50,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 25,000.00** equivalent in USD as a Cash Deposit.
6	**Ciprofloxacin Hydrochloride USP 42** 'Moderately fine powder' Particle size : Pass through 45 mesh - N.L.T. 95% Pass through 80 mesh - N.M.T. 40%	25 kg nett in air-tight, light resistant, strong, well closed, seaworthy fiber or plastic drums. Store at 25°C. Each and every drum should be wrapped with polythene.	**1,000kg**	**1,000 kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 100,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 50,000.00** equivalent in USD as a Cash Deposit.
7	**Clarithromycin USP 42** Specifications : 'Fine powder'	25kg. Nett in air-tight, seaworthy, light resistant, strong, well closed, fiber or plastic drums. Each and every drum should be wrapped with polythene.	**2,500kg**	**2,500 kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs.2,000,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 1,000,000.00** equivalent in USD as a Cash Deposit.

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CLOSING DATE & TIME : 26TH MARCH 2024 at 10.00 HOURS SRI LANKA TIME

ITEM NO.	DESCRIPTION OF ITEM WITH SPECIFICATIONS	PACK SIZE PREFERRED	QUANTITY REQUIRED	DELIVERY REQUIRED IN COLOMBO SRI LANKA	APPRX. VALUE OF BID SECURITY
8	**Diltiazem Hydrochloride USP 42** Specifications : Free flowing material	25kg. Nett in air-tight,strong,well closed , exportworthy, fiber or plastic drums. Each and every drum should be wrapped with polythene.	**2,500kg**	**2,500 kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs.800,000.00** equivalent in USD in the form of a Guarantee. **SL Rs. 400,000.00** equivalent in USD as a Cash Deposit.
9	**Domperidone Maleate BP 2020** Specifications : "Very fine Powder"	25kg. nett in air-tight, strong, well closed, seaworthy fiber or plastic drums. Each and every drum should be wrapped with polythene.	**300kg**	**300 kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 75,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 37,500.00** equivalent in USD as a Cash Deposit.
10	**Enalapril Maleate USP 42** Specifications : "Very fine Powder " Particle size Pass through 120 mesh - N. L.T. 95% Pass through 150 mesh - N.M .T. 40% "White Powder"	25kg. nett in air-tight, strong, well closed , seaworthy, fibre drums. Free from contact with metal. Protect from light Each and every drum should be wrapped with polythene.	**300kg**	**300kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 200,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 100,000.00** equivalent in USD as a Cash Deposit.
11	**Famotidine USP 42** Specifications : "Crystalline Powder "	25kg. Nett in air-tight,strong,well closed , fiber drums Protect from light Each and every drum should be wrapped with polythene.	**2,000kg**	**2,000 kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs.300,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs.150,000.00** equivalent in USD as a Cash Deposit.

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CLOSING DATE & TIME : 26TH MARCH 2024 at 10.00 HOURS SRI LANKA TIME

ITEM NO.	DESCRIPTION OF ITEM WITH SPECIFICATIONS	PACK SIZE PREFERRED	QUANTITY REQUIRED	DELIVERY REQUIRED IN COLOMBO SRI LANKA	APPRX. VALUE OF BID SECURITY
12	**Gabapentin USP 42** Specifications : Compacted Powder Tapped Density : 0.75 - 0.85g/cm^3 **Particle Size Distribution** Retained on 20 mesh - 0- 5% Retained on 80 mesh - 60-90% Passed through 120 M - 5-20% Free from foriegm Matter.	25kg. nett in air-tight, strong,well closed, sea worthy fiber drums. Each and every drum should be wrapped with polythene.	**2,500kg**	**2,500kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 300,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 150,000.00** equivalent in USD as a Cash Deposit.
13	**Gliclazide BP 2020** Specifications : 'Very fine powder'	25kg. nett in air-tight, strong, well closed , light resistant, seaworthy DOUBLE POLYTHENE LINED fiber or plastic drums. Each and every drum should be wrapped with polythene.	**18,000kg**	**9,000 kg - May 2024 to SPMC** **9,000 kg - July 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 4,000,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 2,000,000.00** equivalent in USD as a Cash Deposit.
14	**Indometacin BP 2020** 'Micro fine powder' Average partical size should be less than 45 micro meters.	25 kg nett in air - tight, light resistant, strong, well closed, sea worthy, fiber or plastic drums. Free from contact with metal. Each and every drum should be wrapped with polythene.	**100kg**	**100kg- May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 50,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 25,000.00** equivalent in USD as a Cash Deposit.
15	**Losartan Potassium BP 2020** Specifications : Pass through 200 mesh (80% - 100%)	25kg. nett in air-tight, strong, well closed , seaworthy, DOUBLE POLYTHENE LINED, fibre drums. Each and every drum should be wrapped with polythene.	**10,000kg**	**5,000kg - May 2024 to SPMC** **5,000kg - July 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 2,500,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 1,250,000.00** equivalent in USD as a Cash Deposit.

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CLOSING DATE & TIME : 26TH MARCH 2024 at 10.00 HOURS SRI LANKA TIME

ITEM NO.	DESCRIPTION OF ITEM WITH SPECIFICATIONS	PACK SIZE PREFERRED	QUANTITY REQUIRED	DELIVERY REQUIRED IN COLOMBO SRI LANKA	APPRX. VALUE OF BID SECURITY
16	**Mebendazole USP 42** (Polymorph Type "A") Specifications : * White odourless powder * Particle size : Less than 75 microns (200M) * Material should comply with the 'Appearance of solution' as per BP 2010	25kg. nett in air-tight, strong, well closed , seaworthy, light resistant , moisture proof, fiber or plastic drums. Protect from light. Each and every drum should be wrapped with polythene.	**700kg**	**700 kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 100,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 50,000.00** equivalent in USD as a Cash Deposit.
17	**Metformin Hydrochloride BP 2020** Specifications : "Moderately Coarse Powder" Free Flowing' Retained on 25 mesh -N.M.T. - 5% Retained on 40 mesh -N.M.T. - 20% Accumulated on 60 mesh -N.M.T. - 65% Accumulated on 80 mesh -N.M.T. - 85% Pass through 120 mesh -N.M.T. - 5%	25kg. nett in air-tight, well closed , strong, sea worthy, DOUBLE POLYTHENE LINED HDPE Cylindrical drums with plastic lid and handles. The diameter of the drum mouth should not be less than 35cm and the height of the drum should be appr. 50cm. Only one silica gel pouch (appro.100g pebbles - 15cm x 8cm blue colour silica gel bags) should be inserted between two polythene bags in each container and that should be on top of the drum to avoid forming lumps. Each and every drum should be wrapped with polythene.	**27,000kg**	**9,000kg - May 2024 to SPMC** **9,000kg - July 2024 to SPMC** **9,000kg - August 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 500,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 250,000.00** equivalent in USD as a Cash Deposit.
18	**Phenoxymethylpenicillin Potassium BP 2020** Specifications : Pure White , free from any form of lumps and Yellow or Black particles. Microfine Powder 90% particles less than 45microns Bulk Density NLT 0.35% gml^{-3}	25 kg nett in air -tight, strong, well closed, sea worthy fiber or plastic drums. Protect from light and moisture. Each and every drum should be wrapped with polythene.	**1,500kg**	**1,500kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 200,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 100,000.00** equivalent in USD as a Cash Deposit.

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CLOSING DATE & TIME : 26TH MARCH 2024 at 10.00 HOURS SRI LANKA TIME

ITEM NO.	DESCRIPTION OF ITEM WITH SPECIFICATIONS	PACK SIZE PREFERRED	QUANTITY REQUIRED	DELIVERY REQUIRED IN COLOMBO SRI LANKA	APPRX. VALUE OF BID SECURITY
19	**Prednisolone BP 2020** Specifications : 'Micro fine powder' (Average particle size should be less than 45 micro meters.)	25 kg nett in air - tight, light resistant, strong, well closed, sea worthy, fiber or plastic drums. Each and every drum should be wrapped with polythene.	**1,000kg**	**Delivery by Air Only** **500 kg - May 2024 to SPMC** **500 kg - July 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 1,500,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 750,000.00** equivalent in USD as a Cash Deposit.
20	**Propranolol Hydrochloride BP 2020**	25 kg nett in air - tight, moisture proof, strong, well closed, sea worthy, fiber or plastic drums. Each and every drum should be wrapped with polythene.	**800kg**	**800kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 80,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 40,000.00** equivalent in USD as a Cash Deposit.
21	**Salbutamol Sulphate BP 2020**	25 kg nett in air - tight, strong, well closed, export worthy, fiber or plastic drums. Protect from light. Each and every drum should be wrapped with polythene.	**350kg**	**350 kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 150,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 75,000.00** equivalent in USD as a Cash Deposit.
22	**Spironolactone USP 42** Specifications : Super fine powder (NLT 90%)	25 kg nett in air - tight, strong, well closed, export worthy, fiber or plastic drums. Each and every drum should be wrapped with polythene.	**1,000kg**	**1,000 kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 1,000,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 500,000.00** equivalent in USD as a Cash Deposit.

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CLOSING DATE & TIME : 26TH MARCH 2024 at 10.00 HOURS SRI LANKA TIME

ITEM NO.	DESCRIPTION OF ITEM WITH SPECIFICATIONS	PACK SIZE PREFERRED	QUANTITY REQUIRED	DELIVERY REQUIRED IN COLOMBO SRI LANKA	APPRX. VALUE OF BID SECURITY
23	**Sulfamethoxazole BP 2020** Specifications : "Very Fine Powder " Pass through 120mesh - N.L.T. - 95% Pass through 150mesh -N.M.T. - 40%	25 kg nett in air - tight, strong, well closed, export worthy fiber or plastic drums. Protect from light Each and every drum should be wrapped with polythene.	**4,000kg**	**4,000kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 200,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 100,000.00** equivalent in USD as a Cash Deposit.
24	**Trifluoperazine Hydrochloride BP 2020** Specifications : " Fine Powder "	25 kg nett in air-tight, strong, well-closed, light resistant, seaworthy fiber or plastic drums. Protect from moisture and light. Each and every drum should be wrapped with polythene.	**50kg**	**50kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 75,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 37,500.00** equivalent in USD as a Cash Deposit.
25	**Trimethoprim BP 2020** " Very fine Powder " Particle size: Pass through 120 mesh - (95% - 100%) Pass through 150 mesh - (0% - 45%)	25 kg nett in air-tight, strong, well-closed , moisture proof fiber or plastic drums. Protect from light. Each and every drum should be wrapped with polythene.	**800kg**	**800kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 100,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 50,000.00** equivalent in USD as a Cash Deposit.
26	**Verapamil Hydrochloride BP 2020** Specifications: " Fine Powder'	25 kg nett in air - tight, strong, well closed, light resistant fiber drums. Protect from moisture **WARNING LABEL :** Please attach "skull & the cross bones poison" labels on lid and adjuscent to LHS of main label/ title on drum in Black & White. Each and every drum should be wrapped with polythene.	**400kg**	**400 kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 150,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 75,000.00** equivalent in USD as a Cash Deposit.

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TENDER REF. : SPMC/01/2024 CLOSING DATE & TIME : 26TH MARCH 2024 at 10.00 HOURS SRI LANKA TIME

ITEM NO.	DESCRIPTION OF ITEM WITH SPECIFICATIONS	PACK SIZE PREFERRED	QUANTITY REQUIRED	DELIVERY REQUIRED IN COLOMBO SRI LANKA	APPRX. VALUE OF BID SECURITY
27	**Ammonio Methacrylate Copolymer (Type B) USNF 42** Sepecifications: **Particle size :** NLT 90% passes through 42 mesh (350 µm) and NMT 40% passes through 200 mesh (74µm)	In suitable exportworthy air -tight Container Temperature not exceeding 30˚C Each and every drum should be wrapped with polythene.	**3,000kg**	**3,000kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 800,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs.400,000.00** equivalent in USD as a Cash Deposit.
28	**Colloidal Silicon Dioxide USP 42, USNF 37 or Colloidal Anhydrous Silica BP 2020**	10 kg or less nett in air- tight, strong, well closed, moisture proof multiply paper bags. **Avoid polypropylene woven bags.** Each and every container should be wrapped with polythene	**700kg**	**350kg - May 2024 to SPMC** **350kg - July 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs. 50,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 25,000.00** equivalent in USD as a Cash Deposit.
29	**DC Lactose/ Lactose USNF 37 (ANHYDROUS) USP 42** Specifications: **(Direct Compression Grade)**	25 kg nett in air-tight, strong, well closed , exportworthy, fiber or plastic drums/ bags. Protect from light Avoid polypropylene woven bags. Each and every drum should be wrapped with polythene.	**14,000kg**	**7,000kg - May 2024 to SPMC** **7,000kg - July 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs. 400,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 200,000.00** equivalent in USD as a Cash Deposit.
30	**Di-basic Calcium Phosphate (Dihydrate) BP 2020/ USP 42** Specifications: Fine powder as Dihydrate	25 kg nett in Air-tight, well closed, moisture proof fiber or plastic drums or export worthy bags. **Avoid polypropylene woven bags.** Each and every drum or bag should be wrapped with polythene.	**5,000kg**	**5,000kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs.40,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 20,000.00** equivalent in USD as a Cash Deposit.
31	**Hydroxypropylcellulose (L-Type) USNF 37/ USP 42/ BP 2020** Specification Viscosity : 8-10cps at 20^{0}C (In 2% solution) White to cream colour granuler solid or powder	25 kg nett in air-tight, strong, well closed , exportworthy fiber or plastic drums. Each and every drum should be wrapped with polythene.	**1,000kg**	**1,000kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 200,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 100,000.00** equivalent in USD as a Cash Deposit.

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TENDER REF. : SPMC/01/2024 CLOSING DATE & TIME : 26TH MARCH 2024 at 10.00 HOURS SRI LANKA TIME

ITEM NO.	DESCRIPTION OF ITEM WITH SPECIFICATIONS	PACK SIZE PREFERRED	QUANTITY REQUIRED	DELIVERY REQUIRED IN COLOMBO SRI LANKA	APPRX. VALUE OF BID SECURITY
32	**Hypromellose 2910 USP 42** (Benecel E6 Pharm) Very Fine Powder Viscosity Type - 6MPa/s pH- 4.8 - 7.2	25 kg nett in air-tight, strong, well closed , fibre drums. Each and every drum should be wrapped with polythene.	**1,000kg**	**1,000kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs. 40,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs.20,000.00** equivalent in USD as a Cash Deposit.
33	**Lactose BP 2020 (100 mesh)** **(Apen. XVI, B) or Lactose monohydrate USNF 37/USP 42**	25kg nett in strong, well-closed, Air - tight , Multy -Ply paper Bags with a Double Polythene Inner Bag. **Avoid polypropylene woven bags.** Each and every container should be wrapped with polythene.	**1,500kg**	**1,500kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs. 25,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 12,500.00** equivalent in USD as a Cash Deposit.
34	**Lactose BP 2020 (200mesh)** **(Apen. XVI, B) or Lactose monohydrate USNF 37/USP 42** Specification Crystalline Powder	25kg nett in strong, well-closed, Air - tight , Multy -Ply paper Bags with a Double Polythene Inner Bag. **Avoid polypropylene woven bags.** Each and every container should be wrapped with polythene.	**80,000kg**	**40,000kg - May 2024 to SPMC** **40,000kg - July 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs. 800,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 400,000.00** equivalent in USD as a Cash Deposit.
35	**Magnesium Stearate BP 2020** Tabletting Grade (Lubricant)	25kg. nett in air-tight , well closed, exportworthy fiber drums. Each and every drum should be wrapped with polythene.	**2,000kg**	**2,000kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs. 20,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 10,000.00** equivalent in USD as a Cash Deposit.
36	**Maize Starch BP 2020** Specification Viable Counts to comply with USNF 37/BP 2020 Iron should be less than 5ppm	25kg. nett in strong, well-closed, Multy-Ply Paper bags with a double polythene inner bag. Avoid polypropylene woven bags. Each and every bag should be wrapped with polythene.	**36,000kg**	**9,000kg - May 2024 to SPMC** **9,000kg - June 2024 to SPMC** **9,000kg - July 2024 to SPMC** **9,000kg - August 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 2 years) at the time of receipt in Sri Lanka.**	**SL Rs. 100,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs.50,000.00** equivalent in USD as a Cash Deposit.

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TENDER REF. : SPMC/01/2024 CLOSING DATE & TIME : 26TH MARCH 2024 at 10.00 HOURS SRI LANKA TIME

ITEM NO.	DESCRIPTION OF ITEM WITH SPECIFICATIONS	PACK SIZE PREFERRED	QUANTITY REQUIRED	DELIVERY REQUIRED IN COLOMBO SRI LANKA	APPRX. VALUE OF BID SECURITY
37	**Maleic Acid BP 2020** Very Fine Powder	25 kg nett in well closed, Air -tight, Moisture proof, Export Worthy fiber or plastic drum. Each and every drum should be wrapped with polythene.	**50kg**	**50kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 10,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs.5,000.00** equivalent in USD as a Cash Deposit.
38	**Microcrystalline Cellulose USP 42 / USNF 37/ BP 2020** Specifications : **Particle Size distribution :** Not more than 1% retain on 60 mesh Not more than 30% retain on 200 mesh	25kg. nett in air-tight , strong, well closed, export fiber drums. Avoid polypropylene woven bags. Each and every drum should be wrapped with polythene.	**12,000kg**	**6,000kg - May 2024 to SPMC** **6,000kg - July 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs. 125,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 62,500.00** equivalent in USD as a Cash Deposit.
38	**Microcrystalline Cellulose LM 200 USNF 37** Specifications : Particle Size distribution : Retain on 60 mesh : NLT 10% Retain on 100 mesh : NLT 50% Moisture : Max. 1.5% LM Bulk Density : 0.3 - 0.4g/cm^3	25kg. nett in air-tight , strong, well closed, moisture proof, exportworthy fiber or plastic drums. Protect from excessive heat and moisture. Avoid polypropylene woven bags. Each and every drum should be wrapped with polythene.	**10,000kg**	**5,000kg - May 2024 to SPMC** **5,000kg - July 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs. 150,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs.75,000.00** equivalent in USD as a Cash Deposit.
40	**Polyethylene Glycol USP 42 NF 37** Average M. Weight 6000 grade	25kg/ 10 kg nett in strong, air-tight , well closed, fiber or plastic drums. Each and every drum should be wrapped with polythene.	**300 kg**	**300kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs. 15,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs.7,500.00** equivalent in USD as a Cash Deposit.
41	**Povidone K-30 USP 42 / BP 2020**	25kg nett in air-tight , well closed, fiber or plastic drums. Protect from moisture Each and every drum should be wrapped with polythene.	**2,000kg**	**2,000kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs. 100,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs.50,000.00** equivalent in USD as a Cash Deposit.

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ITEM NO.	DESCRIPTION OF ITEM WITH SPECIFICATIONS	PACK SIZE PREFERRED	QUANTITY REQUIRED	DELIVERY REQUIRED IN COLOMBO SRI LANKA	APPRX. VALUE OF BID SECURITY
42	**Purified Talc BP 2020** Tabletting Grade Pure White fine material Specifications : Labelling: -Product suitable for oral application. - Product does not contain detectable levels of asbestiform, minerals (By X-Ray diffraction methods) - Does not contain Bovine, ovine or caprine materials of any type.	25kg nett in air-tight , well closed, strong fiber drums. (Export Containers) Avoid polypropylene woven bags. Each and every drum should be wrapped with polythene.	**7,000kg**	**3,500kg - May 2024 to SPMC** **3,500kg - July 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs. 25,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 12,500.00** equivalent in USD as a Cash Deposit.
43	**Sodium Starch Glycolate BP 2020 (Type A) USNF 37** Specifications: "Very fine powder " pH : 5.5 -7.5 (90% of the particles should be less than 175 micro meters - 80 mesh) Swelling capacity Test : 1g in 100ml of water should swell above 30cm within 2 hours.	25 kg. nett in air-tight , strong, well closed, fiber drums and protect from light, heat and humidity. Each and every drum should be wrapped with polythene.	**4,000kg**	**4,000kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs. 70,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 35,000.00** equivalent in USD as a Cash Deposit.
44	**Stearic Acid BP 2020** (Grade 50)	25 kg nett in air-tight, strong, well closed , moisture proof containers. Each and every drum should be wrapped with polythene.	**500 kg**	**500kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 3 years) at the time of receipt in Sri Lanka.**	**SL Rs. 10,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 5,000.00** equivalent in USD as a Cash Deposit.
45	**Titanium Dioxide BP 2020** 'Fine powder' (For pharmaceutical use)	25 kg nett in air-tight, strong, well closed , moisture proof container/drum. Each and every drum should be wrapped with polythene.	**700kg**	**700kg - May 2024 to SPMC** **At least 2/3rd of residual shelf life (subject to a minimum of 4 years) at the time of receipt in Sri Lanka.**	**SL Rs. 15,000.00** equivalent in USD in the form of a Guarantee. **OR** **SL Rs. 7,500.00** equivalent in USD as a Cash Deposit.

12……/-

NOTE

** Bids are administered by the provisions of the " Public Contract Act No. 3 of 1987" and therefore , in the event bidder is to be retained an Agent , sub Agent, Representative Nominee for and on behalf of bidder shall register himself any such Public Contract in accordance with the section 10 of the Public Contract Act and produce such valid certificate of registration in the course of any transaction relating to the tender or act any stage in the duration of the tender.

Bid Security (Refer clauseITB 13) & ITEM SCHEDULE I

PLEASE STRICTLY ADHERE THE CLAUSE NO. ITB 9(f) (SAMPLE SUBMISSION PROCEDURE)
PLEASE SUBMIT :SUPPLIER APPROVAL QUESTIONNAIRE" WITH THE TENDER SAMPLES.
PLEASE STRICTLY ADHERE THE CLAUSE NO. GCC 11 (PAYMENTS / LETTER OF CREDIT)

Specification : Where the abbreviations "BP" or "USP" and "IP" are mentioned, the product should meet the specifications of the BP 2020 , USNF 37 USP 42 (and supplement 1 to 4) , the latest Indian Pharmacopoeia and all amendments to these pharmacopoeia; in addition to any other specifications we have mentioned.

For all the items :

* **Use separate copies of "Statement of Compliance" (Schedule II(b)) for each item offered by you.**
* **Price should be quoted only C&F basis.**
* Date of Manufacture , Date of Expiry, Lot No. and Drum Nos. or Bag Nos. should be indicated on the label.
* Bidder should indicate the name of the manufacturer.
* **Local Agent commission should be indicated in your bid.**
* **Original and Copy of the the offer should be typed and signed by Authorized Signatories. Any changes should also be initialled.**
* **Please attached a copy of "Company Registration" of "Local Agent" and the "Bidder".**
* **Please attached a "GMP Certificate" with "Product List " from the manufacturer.**

FOR ACTIVE PHARMACEUTICAL INGREDIENTS (API'S)

* **The bidder shall be responsible to submit the "Drug Master File & certificate of suitability " (for European origin) along with acceptance of the awarding.**