

# Notice Inviting e-Tender

**West Bengal Medical Services Corporation Limited**  
**Swasthya Bhawan Complex**  
**GN-29, Salt Lake, Sector-V**  
**Kolkata - 700091**

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**NOTICE INVITING TENDER FOR SUPPLY OF *Antimalarial Drugs***  
(Submission of Bid through *online*)

Bid Reference No: **WBMSCL/NIT-33/2014**

Dated-06.05.2014

## *Table for Important Dates*

<b>Sl.</b>	<b>Items</b>	<b>Publishing date(s)</b>
1.	Date of uploading of N.I.T. Documents (online)/ Date of Issue	06.05.2014
2.	Documents download start date (Online)	06.05.2014
3.	Date of <b>Pre Bid Meeting</b> with the intending Tenderers in the Conference Hall of <b>West Bengal Medical Services Corporation Limited</b>	13.05.2014 at 3:00 PM
5.	Bid submission start date (On line)	14.05.2014 at 11:00 AM onwards
6.	Documents download end date (Online)	N.A.
7.	<b>Bid submission closing (On line)</b> Bid submission includes: i) Non statutory documents to be submitted under <u>My Space</u> (Each sub-category item should be in multiple page single PDF file) ii) BID – A (Should be in multiple page single PDF file) iii) BID – B (Should be in multiple page single PDF file) iv) BID – C (BOQ and the statement of Breakup of Duties and Taxes) <b>Detailed list of documents annexed at Section V Check-List Form</b> Non-statutory document (document uploaded in <u>My Space</u> ), Bid – A & Bid – B constitute the technical bid and Bid – C is the financial bid. <b><i>Any wrong or misleading information provided by the Tenderer during submission of bids shall lead to summary cancellation of bid and may lead to blacklisting in WBMSCL for at least 3 years.</i></b>	20.05.2014 up to 5:00 PM

	<b>Each scanned documents should have an index page indicating the name of the documents enclosed with page number.</b>	
8	<p><b>Last date of submission of</b></p> <p>a) Cost of Earnest Money Deposit ( Demand Draft / Pay Order / Bank Guarantee)</p> <p>b) Hard copies of the documents uploaded in e-tender during bid submission. <b>No BOQ to be submitted in hard copy.</b></p> <p>c) Copy of acknowledgement generated by e-tender portal against the documents uploaded during bid submission.</p> <p>d) 5 (five) strips of the product in a model unit pack.</p> <p>N.B.:</p> <p>1) All the above documents are to be submitted at the registered office of WBMSCL.</p> <p>2) <b>It is essential that all documents in hard copy are to be placed before the Committee and arranged in the same sequence as given in the Check List. All the documents should be appropriately flagged.</b></p>	23.05.2014 up to 3:00 PM
9.	Date of opening of Bid – A & Bid – B (i.e., for technical evaluation) (Online)	23.05.2014 ; 3:00 PM onwards
10.	Bidders to remain present at WBMSCL office, Kolkata for identification of the documents for the technical bid evaluation	To be informed later
11.	Date of opening of Bid – C (i.e., for financial evaluation) (Online)	To be informed later

1. West Bengal Medical Services Corporation Limited (WBMSCL) has been requested by the Government of West Bengal to procure on their behalf Tab. ACT (Adult)-SP + Artesunate and Inj. Artesunate (60 mg) to be supplied to the Districts for supply to various healthcare establishments of the Govt. of West Bengal.
2. WBMSCL hereby invites bids from eligible and qualified Tenderers for the supply of Tab. ACT (Adult)-SP + Artesunate and Inj. Artesunate (60 mg) as per the Schedule of Requirement.
3. Intending Tenderer may download the tender documents from the website: **www.wbtenders.gov.in** Earnest money to be drawn in favour of '**West Bengal Medical Services Corporation Limited**' through Demand Draft / Bank Guarantee issued from any scheduled bank payable at Kolkata.
4. Non statutory documents, Bid – A, Bid – B & Bid – C are to be submitted concurrently.

Sd/-  
**Managing Director**  
**WBMSCL**

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## Section I: Important information at a glance

### **1. Tender schedule in brief:**

<b>Schedule I</b>	<b>Schedule II</b>
Tab. ACT(Adult)- [SP + Artesunate]	Inj. Artesunate (60 mg)
Qty.- 10000	Qty.- 6000

### **2. Tender fees:**

<b>Schedule I</b>	<b>Schedule II</b>
Tab. ACT (Adult)-[SP + Artesunate]	Inj. Artesunate (60 mg)
<i>Tender fees are not required</i>	

### **3. Earnest Money Deposit (EMD):**

<b>Schedule I</b>	<b>Schedule II</b>
Tab. ACT (Adult)- [SP + Artesunate]	Inj. Artesunate (60 mg)
Rs. 15000	Rs. 20000

### **4. Annual Turnover requirements:**

<b>Schedule I</b>	<b>Schedule II</b>
Tab. ACT (Adult)- [SP + Artesunate]	Inj. Artesunate (60 mg)
The Manufacturers or their marketing organization should have annual sales turnover of minimum Rs. 2 (two) crore on an average of last three financial years as per the Audited Accounts of the Organization.	The Manufacturers or their marketing organization should have annual sales turnover of minimum Rs. 2 (two) crore on an average of last three financial years as per the Audited Accounts of the Organization.

### **5. (a) Delivery schedule:**

<b>Delivery Status</b>	<b>Schedule I</b>	<b>Schedule II</b>
	Tab. ACT (Adult)-[SP + Artesunate]	Inj. Artesunate (60 mg)
Start of Delivery	NA	NA
Completion of 50%	NA	NA
Completion of 100%	Within 60 Days	Within 60 Days
Supply with Penalty	Within 70 Days	Within 70 Days
Note 1: Part delivery is not allowed		
Note 2: The delivery schedule will be effective from the date of Award of Work		

**6. (b) Payment Terms for Schedule I & II:**

<b>Payment</b>	<b>Days (with Condition)</b>
30% of the total payment	Will be made within 15 days of completion of total delivery of goods on placement of delivery challans and invoices.
Rest 70% of the total payment	Will be made after WBMSCL satisfied itself that the goods have been delivered as per the specification of or requirements of the tender including packaging and labeling norms and successful quality certification as per provisions in the tender but not beyond 60 days of raising of bills.

**7. Performance Security:**

<b>Schedule I</b>	<b>Schedule II</b>
Tab. ACT (Adult)- [SP + Artesunate]	Inj. Artesunate (60 mg)
The Performance Bank Guarantee of 10% of the Bid value shall remain valid up to not less than 365 days after the last day of supply with additional 30 days for claim period.	

**8. Who can Bid:**

<b>Schedule I</b>	<b>Schedule II</b>
Tab. ACT (Adult)- [SP + Artesunate]	Inj. Artesunate (60 mg)
a) Manufacturing Company b) Marketing Organization, duly authorized by the Manufacturer c) Joint Venture (JV) - Only among the Manufacturers. d) Consortium- Only among the Manufacturers. <b>Note:</b> JV / Consortium may be of maximum 3 (three) members.	

**9. Eligible Tenderers:**

8.1 a) A Tenderer, and all parties constituting the Tenderer, may have the nationality of any country.

b)

<b>Schedule I</b>	<b>Schedule II</b>
Tab. ACT (Adult)- [SP + Artesunate]	Inj. Artesunate (60 mg)
Tenderer should have manufactured & supplied at least 5 lakh number tablet of any drugs or medicine to at least one national programme/ government (state/central) in India in last 5 years.	Tenderer should have manufactured & supplied at least 3 thousands Inj. of any drugs or medicine to at least one national programme/ government (state/central) in India in last 5 years.

**8.2 A Tenderer shall not have a conflict of interest.** All Tenderers found to have conflict of interest shall be disqualified. Tenderers may be considered to have a conflict of interest with one or more parties in this bidding process if he submits more than one bid in this bidding process either directly or through any subsidiaries or any associates of any organization.

8.3 A constituent of one Tenderer cannot be the constituent of another Tenderer (in case of JV / Consortium).

**Explanation:** In case a Tenderer is a Consortium, then the term Tenderer as used in this Eligible Tenderers shall include only the Lead Member of such Consortium.

8.4 If any Tenderer or any Associate thereof has participated as a consultant to the Authority in the preparation of any documents, design or technical specifications of this bid, he is not eligible to apply.

8.5 Tenderers shall not be eligible to submit a bid when at the time of bid submission the Tenderer has been suspended and declared ineligible by WBMSCL or the Government of West Bengal or the Central Government.

8.6 In the case of a JV, Bids may be submitted by a Joint Venture through a duly filled JV partner information form (enclosed as Form 4 of Section V)

- a. The duly filled Joint Venture Partner Information Form must be included with the Bid;
- b. All parties to the JV shall be jointly and severally liable;
- c. The JV shall nominate a Representative who shall have the authority to conduct all businesses:
  - For and on behalf of any and all the parties of the JV during the bidding process; and
  - In the event the JV is awarded the Contract, during contract execution.

**Explanation:**

In the event of a Joint Venture being selected for contract award, the Contract Agreement can only be in the name of the Joint Venture and all payments will be made in name of JV. Any request, declaration or agreement by any or all member of JV to the contrary will not be accepted and the Award of work will be cancelled or terminated as the case may be.

8.7 Drugs should be manufactured in WHO GMP, cGMP and ISO certified manufacturing unit under revised Schedule-M/ Schedule-M III . Bid may be submitted by Drug manufacturing unit(s), JV or Consortium of valid pharmaceutical manufacturers or their marketing organization with such other manufacturer(s).

8.8 It may be noted that the consortium or JV will be allowed with maximum Three Manufacturer members only and the change in membership or pattern of membership of consortium or JV will not be allowed during the entire period of Contract.

8.9 The required production capacity of the tenderer in their own factory or in accumulation of the production capacities of the factories of their JV or consortium members is given below,



<b>Schedule I</b>	<b>Schedule II</b>
Tab. ACT( Adult)-[SP + Artesunate]	Inj. Artesunate (60 mg)
1 lakh number/month	10 thousand number/month

8.10 The manufacturer may supply directly or can authorize one distributor only. In the event of manufacturer authorizing supply through distributor, the distributor should comply with following criteria:

- a) Having distributorship of at least for last 3 years with the concerned manufacturer.
- b) Having turnover of an average of at least Rs. 20 (twenty) lakh during last three financial years.
- c) Must have experience of Government supply in the last three financial years in West Bengal.
- d) Must have valid drug licence.

8.11 Manufacturers having up to date valid Drug Manufacturing License will be allowed to quote for Drugs as per the Drugs and Cosmetics Act 1940 by the Govt. of India. For marketing organizations, the manufacturing licence of the manufacturer needs to be submitted along with the valid Drug distribution Licence.

#### **8.12 Annual Turnover:**

<b>From Schedule I to II</b>
a) The manufacturers or their marketing organization should have annual sales turnover as as per table – 4 Annual Turnover Requirement of Section I: Important information at a glance as per the audited accounts of the organization to qualify in each schedule.
b) In the event of manufacturer authorizing supply through distributor, the distributor must have a turnover of an average of at least Rs. 20 (twenty) lakh for all the schedules taken together during the last three financial years in addition to the specified turnover of the manufacturer or their marketing organization.

#### **8.13 Preference for S.S.I. units registered in West Bengal & PSUs in West Bengal:**

Preference will be given to the S.S.I. units registered in West Bengal & PSUs in West Bengal and State Based Other Manufacturers as per West Bengal Financial Rule incorporated under notification No. 10500-F dated 19.11.04 as amended hereafter.

**9. Guidelines for uploading documents in My Space :**

Sl · No.	Category Name	Sub- Category Name	Document Name
1	CERTIFICATES	CERTIFICATES	<ul style="list-style-type: none"> <li>a) PAN Card of the bidder</li> <li>b) VAT Registration of the bidder</li> <li>c) CST registration of the bidder</li> <li>d) WHO GMP and cGMP Certificate of the manufacturer</li> <li>e) Revised schedule M III Certificate</li> <li>f) ISO 13485 of the manufacturer</li> <li>g) CE Certificate of the Manufacturer</li> </ul>
2	COMPANY DETAILS	COMPANY DETAILS 1	<ul style="list-style-type: none"> <li>a) Licence from Government/ Statutory Authority of the bidder as Applicable</li> <li>b) Factory Licence of the manufacturer</li> </ul>
		COMPANY DETAILS 2	<ul style="list-style-type: none"> <li>a) Valid Drug Manufacturing Licence of the manufacturer</li> <li>b) Valid Drug distribution Licence in case of marketing organization</li> <li>c) Current registration as SSI (if any)</li> </ul>
3	CREDENTIAL	CREDENTIAL 1	Performance Statement Form (For the period of last three financial years) - Form 6 of Section V <b>To attach:</b> Documentary evidence (Client's certificate) in support of satisfactory completion of above orders.
		CREDENTIAL 2	
4	DECLARATION	DECLARATION1	Income Tax returns and acknowledgement receipt for assessment year 2013-14
		DECLARATION2	VAT returns and acknowledgement receipt for assessment year 2013-14
		DECLARATION3	
		DECLARATION 4	Legal declaration affirmed before a First Class Magistrate / Notary on non judicial stamp paper of Rs. 100/- for, <ul style="list-style-type: none"> <li>a) Acceptance of Terms and Conditions of NIT and its Amendments and Addendums thereto. (As per Form 3 of Section V).</li> </ul> <p><b>Note:</b> Technical evaluation of the bid will be taken up only after scrutiny of Form 3 (NIT Acceptance Form) duly notarized.</p>

		DECLARATION 5	Legal declaration affirmed before a First Class Magistrate / Notary on non judicial stamp paper of Rs. 100/- for,  <b>No Adverse Report &amp; No Conviction Certificate (Form 7)</b>
	EQUIPMENT	MACHINERIES 1	Manufacturer's Authorization (If applicable) as per Form 8 of Section V
		MACHINERIES 2	
		MACHINERIES 3	
		MACHINERIES 4	
6	FINANCIAL INFO	P/L & BALANCE SHEET 2011-2012	P/L & Balance sheet for last completed calendar year/Financial year as applicable 2012-2013
		P/L & BALANCE SHEET	
		P/L & BALANCE SHEET	

N.B.: Required documents in sub- category should be uploaded in multiple page single PDF file.

\*(In case of Consortium, documents of the Lead Member should be uploaded)

## **10. Bid:**

### **10.1 Bid – A:**

EMD (Scanned copy of the instrument through which EMD have been submitted)

### **10.2 Bid - B:**

- a) Name of the offered Item (Self Declaration)
- b) Certificate for 3 years market standing from a Chartered Accountant for the offered drugs/ medicine (having same specification as given in this bid document). A copy of valid manufacturing licence along with list of approved drugs valid for those 3 years should also be enclosed in support
- c) Copy of the Order/s and proof of payment for supplying items (in support of the eligibility criteria mention in **table 8.1 (b) - under Eligible Tenderers**) to at least one national programme/ government (state/central) in India in last 5 years.
- d) Documentary evidence of manufacturing capability (in support of the eligibility criteria mention in **table under clause 8.9 - under Eligible Tenderers**)
- e) Test report of the manufacturer to be submitted by the Tenderer in respect of the batch for which sample has been submitted.
- f) Documentary evidence in regards to bio-compatibility of the device as per the requirements given in "Biological Evaluation of Medical Devices" IS 12572
- g) Certificate of analysis of Polydimethylsiloxane (Used for lubrication) Confirming to the requirements of IP

### **10.3 Bid - C: BoQ (Bill of Quantity)**

GROSS PRICE of the goods is to be quoted. GROSS PRICE of goods includes value of the goods including all charges and taxes (including 1% entry tax) for supply at the door step of the consignees.

Comparison of financial bid will be based on '**GROSS PRICE**'

Rates shall be valid throughout the period to be covered by the contract to be executed with successful Tenderers along with any extensions as may be made by the competent authority from time to time.

### **11. Tender Evaluation:**

11.1 During the tender evaluation process, the 'Bid – A' & 'Bid – B' will be opened first.

11.2 The 'Bid - C' (Financial Bids) of only those Tenderers qualifying in the technical bid will be opened.

11.3 Comparison of price will be based on the rate quoted according to '10.3' above.

11.4 The objective of this bid is to ensure supply of best quality drugs at the most competitive price. If at any stage of the bidding, including at the stage of financial evaluation, it appears that the quoted rate is artificially hiked compared to the prevailing market price, WBMSCL reserves the right to cancel the bids at any stage of evaluation.

### **12. Drugs Licence:**

(Only In Cases where applicable- Applicability to be determined by the State Drug Control Authorities)

Copy of Drug Licence with current validity certificate along with full list of endorsement with items highlighted by colouring / underlining of medicine and medical device quoted in the tender must be submitted.

### **13. Quality Testing:**

Nothing in this clause will bar WBMSCL from getting the medicines inspected from any NABL Accredited Laboratory of its choice. Provided further that in case the quality tests report done by WBMSCL states that the medicine to do not conform to the accepted quality standard, WBMSCL will impose penalty as per clause laid down in Special Conditions of Contract. The decision of WBMSCL in matters of quality after the said quality test would be final.

a) West Bengal Medical Services Corporation Limited and the heads of the direct demanding units and decentralized stores will be at liberty to get the items supplied tested at Govt. selected/ empanelled laboratory, including NABL accredited laboratories, Govt approved Test Houses, BIS Labs etc., the identity of which shall not be divulged to the Tenderer. Such testing will be in addition to tests that may be done by any authority exercising statutory powers of drug/medical device testing. The Tenderer shall be bound to destroy the defective batch(s) as per test report of either the non-statutory lab or the statutory lab. The cost of procurement of non-standard items will be deducted from the Security Deposit, Performance Bank Guarantee and/or from the pending bills of that supplier. Moreover, action under relevant Rules of the Drugs and Cosmetic Act will also be taken.

In no circumstances request for replacement of non-standard medical devices or equipment by the suppliers will be entertained.

- b) A sum@ 2% of bills exclusive of Govt. tax & duties will be deducted from the bills of the supplies of items included in this tender by WBMSCL and deposited in the respective budget head to meet cost of handling and testing charges.

**14. *Withdrawal /Cancellation & Purchase Policy of Tendering Authority:***

- i) The tendering authority reserves the right to withdraw any item from the tender at any stage. The selection of such item, if already made in favour of any Tenderer, shall be treated as cancelled.
- ii) The tendering authority reserves the right to reject or accept any tender or part thereof at any stage or to split any tender without assigning any reason. Withdrawal of tender or any revision after submission of tender by the Tenderer will not be allowed.
- iii) Purchase will; however, be made following the existing purchase policy of the Govt of West Bengal and its amendment(s) made from time to time.
- iv) In case of inability to supply ordered quantity in the stipulated time period, the tendering authority reserves the right to purchase the required quantity not supplied from the open market. In that case the difference of cost, if any, will be recovered from the Performance Security of the selected supplier.
- v) The tendering authority reserves the right to accept or reject any tender, in part or in full, without assigning any reason.

**15. *No- Conviction Certificate:***

Manufacturers will submit an affidavit as per Form 7 of Section V attached herewith from first class Judicial Magistrate / Notary Certificate.

**16. *Contract / Agreement:***

On being selected as L1 Tenderer, intimation of selection will be forwarded to the Tenderer by WBMSCL. After that the Tenderer will have to execute an agreement in the prescribed form with West Bengal Medical Services Corporation Limited. This present document and the tender forms filled in by the Tenderer or copies thereof in so far as they are not inconsistent with these terms & conditions will be incorporated as part of the agreement. Such agreement will be binding on the Tenderer.

**17. *Validity Period of Agreement:***

The contract period will remain valid for a period of 365 days from the date of completion of total supply.

**18. *Order & Supply:***

Orders for the supply of estimated quantities of items in this tender will be placed with the successful tenderer after the execution of the agreements, and such supply shall have to be made in such instalments as may be fixed or spread over the period to be specified in the supply orders to be made in pursuance of the agreement.

**19. *Performance Security (In the Form of Bank Guarantee):***

- (i) The performance bank guarantee will be mandatory for the selected supplier(s) and will not be waived in any case.
- (ii) The 'Performance Bank Guarantee' will be as per table 6 - Performance Security of Section I: Important information at a glance.
- (iii) The Performance Bank Guarantee from any nationalized/ scheduled bank in India as per model proforma (Form 9) of Section V should be submitted to the Managing Director, West Bengal Medical Services Corporation Ltd., within 2 weeks from the date of Letter of Acceptance (LOA).

- (iv) The Performance Bank Guarantee will be liable to forfeiture in the event of termination.
- (v) The Performance Bank Guarantee shall remain valid up to not less than 365 days after the last day of supply with additional 30 days for claim period.

## ***20. Inspection:***

The competent authority of West Bengal Medical Services Corporation Limited may visit the factory as and when required for inspection.

## **Section II: General Conditions of Contract (GCC)**

In the event of an order, the WBMSCL General Conditions of Contract will apply as under

### **1. *Legal Status of the Parties:***

WBMSCL and the Vendor shall respectively be referred to as "FIRST PARTY" & "SECOND PARTY" hereunder and each Party acknowledges and agrees that:

- 1.1 Nothing contained in or relating to the contract shall be construed as establishing or creating between the Parties the relationship of employer and employee or of principal and agent. The officials, representatives, employees, or subcontractors of each of the Parties shall not be considered in any respect as being the employees or agents of the other Party and each Party shall be solely responsible for all claims arising out of or relating to its engagement of such persons or entities.
- 1.2 If the Tenderer is a joint venture (JV) or consortium, all of the Parties shall be jointly and severally liable to WBMSCL for the fulfilment of the provisions of the Contract and shall designate one party to act as a leader with authority to bind the joint venture or consortium even though the Award of Work will be issued in the name of JV and all payment will be made in the name of JV. In case of Consortium, the Award of Work will be issued in the name of the Lead Partner of the Consortium and all payment will be made in the name of the Lead Partner. The composition or the constitution of joint venture or consortium shall not be altered without the prior consent of WBMSCL.

### **2. *Definitions:***

- 2.1 GOODS: Goods are hereinafter deemed to include, without limitation, such medicines, raw materials, components, intermediate products and products which the Tenderer is required to supply pursuant to the Purchase Order or Special Conditions of this Contract to which these General Conditions are attached. Services are hereinafter deemed to include services ancillary to the supply of the Goods including, without limitation transportation and supply at the point of consignee and such other obligations as required under this Contract.
- 2.2 TRADE TERMS: Whenever an Inco term is used in this Contract it shall be interpreted in accordance with the Inco terms 2010.

### **3. *Contract Price:***

Prices charged by the Tenderer for the Goods supplied and the related services performed under the Contract shall not vary from the prices quoted by the Tenderer in its bid, with the exception of any price adjustment authorized in writing by WBMSCL.

### **4. *Penal Provisions under the Contract***

WBMSCL will maintain Tenderer history for all Tenderers. The penal norms as described in **Section III Special Condition of Contract** will follow in general in case of Tenderers who fail to abide by the contract norms. The penal action for repeated offence by the same

Tenderer will attract penal provision as stated even if the offence is made against the same contract or against a different contract period of the first contract.

In case a drug is found to be spurious, mislabelled, misbranded, sub-standard, recycled or a combination of any of these on first verification by WBMSCL, the sample will be sent to Director Drug Control for statutory examination and taking further penal action as per Drugs and Cosmetics Act 1940, Drugs and Cosmetics Rules 1945 and amendments thereafter.

## **5. *Acceptance of Goods:***

5.1 Under no circumstances shall WBMSCL be required to accept any Goods (including packaging and labelling of goods) that do not conform to the specifications of requirements of the Contract.

5.2 The expiry of the goods supplied by the Vendor shall be valid for minimum of two years from the date of delivery of the last consignment.

## **6. *Title:***

Unless otherwise expressly provided in the Contract, title in and to the Goods shall pass from the Tenderer to WBMSCL upon delivery of the Goods and their acceptance by WBMSCL in accordance with the requirements of the Contract.

## **7. *Warranty of Goods:***

Without limitation of any other warranties stated in or arising under the Contract, the Vendor warrants and represents that:

7.1 The Goods, including all packaging and packing thereof, conform to the specifications of the Contract, are fit for the purposes for which such Goods are ordinarily used and for the purposes expressly made known in writing by WBMSCL to the Tenderer, and shall be of even quality, free from faults and defects in material and manufacture under normal use in the conditions prevailing in the country of final destination;

7.2 The Goods are of the quality, quantity and description required in the Contract;

7.3 The Goods are free from any right of claim by any third-party and unencumbered by any title or other rights, including any liens or security interests and claims of infringement of any intellectual property rights, including, but not limited to, patents, copyright and trade secrets.

## **8. *Indemnification:***

The Tenderer shall indemnify, defend and hold the WBMSCL, the DoHFW and the Government agencies harmless against any or all proceedings, actions and third party claims arising out of a breach by the Tenderer of any of its obligations under this agreement.

This indemnity shall be limited in respect of making harmless to the WBMSCL, the DoHFW and the Government agencies.



## **9. Changes:**

WBMSCL may at any time by written instruction vary the general scope of this Contract by twenty percent (20%) of the quantity above or below the original Contract.

## **10. Termination for Convenience:**

10.1 WBMSCL may, upon notice to the Tenderer, terminate this Contract, in whole or in part, at any time for its convenience. The notice of termination shall state that termination is for WBMSCL's convenience, the extent to which performance of the Vendor under the Contract is terminated and the date upon which such termination becomes effective.

10.2 In the event of Termination for Convenience, no payment shall be due from WBMSCL to the Tenderer except for Goods satisfactorily delivered and for the cost of such necessary work as WBMSCL may request the Tenderer to complete.

## **11. Termination for Default:**

11.1 WBMSCL, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Vendor, may terminate the Contract, in whole or in part if:

11.1.1 The Vendor fails to deliver any or all of the Goods within the period specified in the Contract:

11.1.2 The Vendor fails to perform any other obligation under the Contract;

11.1.3 The Vendor, in the judgment of WBMSCL, has engaged in fraud and corruption, in competing for or in executing the present Contract:

11.1.4 The Vendor attempts to offer any direct or indirect benefit arising from or related to the performance of the Contract or the award there of to any representative, official, employee or other agent of WBMSCL or any organization of Health & Family Welfare Department, Government of West Bengal:

11.1.5 The Vendor is adjudged bankrupt, or is liquidated, or becomes insolvent, applies for moratorium or stay on any payment or repayment obligations, or applies to be declared insolvent;

11.1.6 WBMSCL reasonably determines that the Vendor has become subject to a materially adverse change in its financial condition that threatens to endanger or otherwise substantially affect the ability of the Vendor to perform any of its obligations under the Contract.

11.1.7 Non compliance of all statutory norms and applicable laws relating to the said contract will entitle WBMSCL to terminate the contract.

11.2 Upon occurrence of one or more of the events specified above, WBMSCL shall follow the procedure of issuing notice or show cause specifying the time frame and on being not satisfied with the explanation, be entitled to terminate the Contract immediately. The decision of WBMSCL shall be final and binding on the Tenderer.

## 12. *Penalty for Default:*

In case of failure by the Tenderer to perform according to this Contact, including but not limited to failure to obtain necessary export licenses or to make delivery of all of the Goods by the agreed delivery date, after giving the Tenderer written notice to perform, and without prejudice to any other rights or remedies available to WBMSCL. The Company may exercise one or several of the penal provisions listed below: -

Nature of offence	Penalty to be imposed
Any wrong or misleading information provided by the Tenderer during submission of bids	May lead to blacklisting in WBMSCL for at least 3 years
Spurious / Mislabeled / Misbranded	Termination of Contract. Blacklisting for life. Forfeiture of the Performance Bank Guarantee. Lodging FIR.
Sub-standard after part of the same is consumed	Free of charge fresh supply. Destruction of substandard Drug. In case, drug is to be procured from any other source, the difference in cost is to be borne by the vendor. Forfeiture of the Performance Bank Guarantee.
Entire supply being Sub-standard	Free of charge fresh supply. Destruction of substandard Drug. In case, drug is to be procured from any other source, the difference in cost is to be borne by the vendor. Forfeiture of the Performance Bank Guarantee. Blacklisting for 3 years
Non-compliance of labeling & packing Norms	Return of goods with warning. Free of charge Replacement. In case, drug is to be procured from any other source, the difference in cost is to be borne by the vendor.
Non execution of agreement or non-compliance of Bid norms after Award of Contract.	Forfeiture of the Performance Bank Guarantee. Blacklisting for 5 years
Delayed supply	In case, drug is to be procured from any other source, the difference in cost is to be borne by the vendor. Delay beyond specified day of supply with penalty [as per table 4(A)] for schedule I to schedule IV Termination of contract and forfeiture of performance security

### **13. Confidentiality:**

- 13.1 WBMSCL and the vendor, its agents, employees, subcontractors and servants shall keep confidential and shall not, without the written consent of the other party hereto, divulge to any third party any documents, data, or other information furnished directly or indirectly by the other party hereto, in connection with the Contract, whether such information has been furnished prior to, during or following competition or termination of the contract. Notwithstanding the above, the vendor may furnish to its subcontractor such documents, data, and other information it received from WBMSCL to the extent required for the subcontractor to perform its work under the contract, in which event the vendor shall obtain from such subcontractor an undertaking of confidentiality similar to that imposed on the vendor.
- 13.2 WBMSCL shall not use such documents, data and other information received from the vendor for any purpose unrelated to the contract. Similarly, the vendor shall not use such documents, data and other information received from WBMSCL for any purpose other than the performance of the contract.
- 13.3 The obligation of a party under the two foregoing paragraphs shall not apply to information that:
- 13.3.1 Now or hereafter enters the public domains through no fault of that party;
  - 13.3.2 Can be proven to have been possessed by that party at time of disclosure and which was not previously obtained, directly, from the other party, or
  - 13.3.3 Otherwise lawfully becomes available to that party from a third party that has no obligation of confidentiality.

### **14. Force Majeure:**

- 14.1 *Force majeure* as used herein means any unforeseeable and irresistible act nature, any act of war (whether declared or not), invasion, revolution insurrection, flood earthquake or any other acts of a similar nature or force, provided that such acts arise from causes beyond the control and without the fault or negligence of the vendor. The vendor acknowledges and agrees that, with respect to any obligation under the contract that the vendor must perform any delays or failure to perform such obligation arising from or relating to harsh conditions within such areas shall not, in and of itself, constitute *Force majeure* under the contract. Further the vendor acknowledges and agrees that scarcity of raw materials, power cut, workers unrest (even if wide spread) will not constitute force majeure under the contract.
- 14.2 In the event of and as soon as possible after the occurrence of any cause constituting *Force majeure*, the vendor shall give notice and full particulars in writing to WBMSCL, of such occurrence or cause if the vendor is thereby rendered unable, wholly or in part perform its obligations and meet its responsibilities under the contract. The vendor shall also notify WBMSCL of any other changes in condition or the occurrence of any event which interferes or threatens to interfere with its performance of the contract. Not more than fifteen (15) days following the provision of such notice *Force majeure* or other changes in conditions or occurrence, the vendor shall also submit a statement to WBMSCL of estimated expenditure that will likely be incurred for the duration of the change in condition or the event. On receipt of notice or notices required hereunder, WBMSCL shall take such action as it considers, in its sole discretion, to be appropriate or necessary in the circumstances, including the granting to the vendor of a reasonable extension of time in which to perform any obligations under the contract.

- 14.3 If an event of *force majeure* exists and the vendor fails, within seven (7) days such event to give notice in writing to WBMSCL pursuant to Article 23.2, and of the vendor is rendered permanently unable, wholly, or in part, by reason of *force majeure* to perform its obligations and meet its responsibilities under the Contract, WBMSCL shall have the right to suspend or terminate the contract on the same terms and conditions as are provided for in Article 19, except that the period of notice shall be seven (7) days, in any case, WBMSCL shall be entitled to consider the vendor permanently unable to perform its obligations under the contract in the case of the vendor's suffering any period of suspension in excess of ninety (90) days.

### ***15. Source of Instructions:***

The vendor shall neither seek nor accept instructions from any authority external to WBMSCL in connection with the performance of its obligations under the contract. Should any authority external to WBMSCL seek to impose any instructions on the vendors regarding the vendor's performance under the contract, the vendors shall promptly notify and shall provide all reasonable assistance required by WBMSCL. The vendor shall not take any action in respect of its performance of the contract or otherwise related to its obligations under the contract that may adversely affect the interests of WBMSCL, and the vendor shall perform its obligations under the contract with the fullest regard to the interests of WBMSCL.

### ***16. Benefits, Corruption and Fraud:***

- 16.1 The vendor warrants that it has not and shall not offer any direct or indirect benefit arising from or related to the performance of the contract or the award thereof to any representative, officials, employee, or other agent of WBMSCL or any official of the Health & Family Welfare department, Government of West Bengal or any organization engaged in the procurement process whether during the period the contract is in process or before or after the contract is over. The vendor acknowledges and agrees that any breach of this provision is a breach of an essential term of the contract as specified.
- 16.2 Corruption means the offering, giving, receiving or soliciting of, directly or indirectly, anything of value to influence the action of any WBMSCL representative, official, employee or agent of WBMSCL or any official of the Health & Family Welfare department, Government of West Bengal or any organization engaged in the selection process or in the execution of the contract.
- 16.3 Fraud means a misrepresentation or omission of facts in order to influence the selection process or the execution of the contract.

### ***17. Use of Name, Emblem or Official Seal of WBMSCL:***

The Vendor shall not advertise or otherwise make public for purpose of commercial advantage or goodwill that it has a contractual relationship with WBMSCL, nor shall the vendor, in any manner whatsoever use the name, emblem or official seal of WBMSCL, or any abbreviation of the name of the WBMSCL or Health & Family Welfare department, Government of West Bengal in connection with its business or otherwise without the written permission of WBMSCL.

### ***18. Assignment:***

- 18.1 The vendor shall not, except after obtaining the prior written approval of WBMSCL, assign, transfer, pledge, or make any other disposition of this contract or any part hereof or of any of the vendor's right or obligations hereunder, except with the prior written authorization of WBMSCL. The vendor may assign or otherwise transfer the contract to the surviving entity resulting from a reorganization of the Party's operations.

18.2 Prior to the written approval of WBMSCL, the vendor shall promptly notify WBMSCL of such assignment at the earliest opportunity subject to the assignee or transferee agrees in writing to be bound by all of the terms and conditions of the contract and such writing is promptly provided to WBMSCL following the assignment or transfer and WBMSCL finds that the vendors has the financial and technical capacity as laid down in the tender document to carry out the assignment provided that:

18.2.1 Such reorganization is not the result of any bankruptcy, receivership or other similar proceedings; and

18.2.2 Such reorganization arises from sale, merger, or acquisition of all or substantially all of the vendor's assets or ownership interest; and

18.2.3 Such reorganization is not taking place with any of the Tenderer who had participated in the Tender or who will be deemed to have conflict of interest as defined in the tender documents process for the same tender.

18.3 However, should the vendor become insolvent or should control of the vendor change by virtue of insolvency, WBMSCL may, without prejudice to any other right or remedy, terminate this contract.

### **19. Taxes:**

Suppliers shall be entirely responsible for all taxes, duties, license fees and entry tax etc., incurred until delivery of the contracted Goods to the ***Consignee as stated in the bid document.***

### **20. Payment Provisions:**

20.1 No advance payment towards startup cost or payment of drug or any other incidental changes will be made to the vendor.

20.2 Payment terms as per 5. (b) - Payment Terms of **Section I: Important information at a glance**

20.3 All Bills/ Invoices should be raised in triplicate in the name of **Managing Director, West Bengal Medical Services Corporation Limited.**

20.4 CENVAT / Deemed Export benefit if enjoyed by the tenderer shall be passed on to WBMSCL.

### **21. Liquidated Damages:**

21.1 Except under the circumstances of *force majeure* as described, if the vendor fails to deliver any or all of the Goods by date(s) of delivery as per conditions of the contract, WBMSCL may, without prejudice to any or all its other remedies under the contract, deduct from the contract price, as per the table attached below as liquidated damages.

Sl. No.	For Schedules	Defaults	Liquidation of the damages
1	Schedules I & Schedules II	Non-completion of scheduled supply	0.5% of the price of goods per week beyond the scheduled date of supply subject to a maximum of 5% of total contract value.

21.2 In case whole or a part of the drug is consumed which is found to be faulty or unfit for consumption or 'NOT OF STANDARD QUALITY' in subsequent period, the entire price of the goods even if consumed will be recovered from the vendor.

**22. *Non-Waiver of Rights:***

The failure by WBMSCL to exercise any rights available to it, whether under the contract or otherwise, shall not be deemed for any purpose to constitute a waiver by WBMSCL of any of its obligations under the contract or in future contracts of similar nature.

**23. *Amicable Settlements:***

When a dispute arises under this agreement the parties shall make all reasonable efforts to resolve through good faith negotiation, failing which they will attempt at dispute resolution with the intervention of the Principal Secretary, the DoHFW, GoWB

**24. *Arbitration:***

Except for a dispute in connection with termination in which respect the decision of WBMSCL shall be final, any dispute between the parties arising out of or relating to this agreement which cannot be resolved through good faith negotiation shall be settled in arbitration in accordance with the provisions of the Arbitration Act. The arbitration hearing shall be held in Kolkata only. The award of the arbitrator (s) shall be binding on both the parties. The cost of arbitration shall be borne by the respective parties.

**25. *Court of Law:***

In case of any dispute in between the parties the matter will be settled in appropriate Court of Law within Kolkata Jurisdiction.

### **Section III: Special Conditions of Contract (SCC) – PENAL PROVISIONS**

The following special conditions of contract (hereinafter referred to as SCC) shall supplement the General Conditions of goods (hereinafter referred to as GCC). Whenever there is a conflict, the provisions herein under SCC shall prevail over those in the GCC.

## **Section IV: Schedule of Requirements**

### **Schedule I**

#### **Technical Specification of Combi Blister Packs for malaria for Adult under NVBDCP**

**A. Description of Stores:** ANTI MALARIAL COMBI BLISTER PACK – Adults  
(WHITE COLOUR Pack)

Total dose of Artesunate – 600 mg divided over 3 (three) days, Sulphadoxine Pyrimethamine - (1500 + 75) mg single dose.

Each Combi Blister containing 3 (three) tablets of Artesunate (each 200 mg ) and 3 (three) tablets of Sulphadoxine Pyrimethamine (500 + 25) mg each.

**Each Row – No. of tablets:**

**First Row (Day 1):** One tablet of Artesunate (200 mg) and 3 (three) tablets of Sulphadoxine Pyrimethamine (500 + 25) mg each.

**Second Row (Day 2):** One tablet of Artesunate (200 mg)

**Third Row (Day3):** One tablet of Artesunate (200 mg)

**-for adult i.e. 15 years & above**

Tablets Artesunate of above strengths to the specifications as per International Pharmacopoeia, latest version.

Tablets Sulfadoxine Pyrimethamine Combination: containing above strength (i.e Sulfadoxine I.P. 500 mg and Pyrimethamine I.P 25 mg per tablet) as per I.P latest version.

**B. Shelf Life/ Efficacy:**

Tablet Artesunate: Two years

Tablet Sulfadoxine + Pyrimethamine two years.

Each Pack will bear shelf life of 2 years on the pack with manufacturing and expiry date.

**C. Packing & Marketing:** The Adult pack will have definite color as indicated above.

The tablets will be placed in 3 (three) rows with transparent top. Each row should be clearly marked as Day 1, Day 2 and Day 3 giving number of tablets in each row.

The pack should indicate dose per kg body weight for both Tablet Artesunate and Tablet Sulfadoxine-Pyrimethamine i.e. AS-4 mg/kg body weight and 25 mg/kg bw of Sulphadoxine + 1.25 mg per kg bw of Pyrimethamine respectively.

All tablets should carry the legend “NVBDCP” on one side .

**Marking:** Printing /marking on Blister / Catch cover/ Corrugated box and pack will be as per Drug & Cosmetics Rules.



Manufacturing and Expiry dates of Artesunate and Sulphadoxine – Pyremethamine tablets should be written separately on the Blister Pack/ Catch Cover.

Each Blister Strip will be stuffed in a paper catch cover. 25 Blister strips will be placed in a pack and 100 such packs will be packed in a corrugated box.

Each Blister Strip/ Catch Cover/Pack and Box should be marked “**NVBDCP SUPPLY- NOT FOR SALE**”.

**D. Final Packing:** Stores shall be securely packed in normal trade packing of Corrugated boxes to avoid loss or damage during the transit by rail/road.

## **Schedule II**

### **Technical Specification of Artesunate Injection Kit under NVBDCP**

#### **A. Specific requirements**

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

#### **Artesunate Injection:**

##### **Description:**

Artesunate Injection contains a sterile powder containing Artesunate.

Each vial shall contain -

Artesunate IP 60 mg

Artesunate Injection complies with WHO working document QAS/10.365/FINAL May 2011 (Adopted text for addition to The International Pharmacopoeia) The powder for injection and the reconstituted injection comply with the monograph for “Parenteral Preparations” included in the latest edition of International Pharmacopoeia.

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

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

#### **Labeling:**

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

**Packing:****Primary Package:**

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

**Sodium Bicarbonate Injection:****Description:**

A clear, colourless solution.

Each ampoule shall contain 1 ml of Sodium Bicarbonate Injection (5%W/v).

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

**Labelling:**

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

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

**Packing:****Primary Package:**

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

**Sodium Chloride Injection:****Description:**

A clear, colourless solution.

Each ampoule shall contain 5 ml of Sodium Chloride Injection (0.9%W/v).

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

**Labelling:**

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

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

**Packing:****Primary Package:**

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

**Secondary Package for Artesunate Injection + Sodium bicarbonate Injection + Sodium Chloride Injection:**

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

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

**Labelling for secondary packaging:**

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

**Quality Assurance:****Compliance:**

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

**Evidence:**

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

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

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

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

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

**Disposable Syringe and Disposable Needle:****Description (Disposable Syringe):**

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

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

Capacity of the Syringe(ml)	Tolerance eq. or ex. to cap.	Tolerance < half of cap.	Max. Dead Vol. (ml)	Length of long Graduation Mark, (mm)	Overall length of Scale, (mm)	Scale interval (ml)	Increment. Between Graduation lines (ml)
05	± 4% of expelled vol.	± 1.5% nominal Cap, + 1% of expelled	0.075	8	36	0.50	1

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

**Description (Disposable Needles):**

Sterile Hypodermic Needles for Single Use comprise of a length of hypodermic grade stainless steel tube connected to a hub that is designed to mate with a syringe or an IV set. They shall conform to the standards given in IS 10654:2002. The other end of the tube is sharpened at the tip as per IS requirements. The tube is covered with a shield made from polypropylene. The hub

fabricated from poly propylene is colour coded as per the requirements of ISO 6009. The union of the hub and needle tube is carried out with epoxy adhesive. This medical device in conjunction with Syringe is intended for immediate use for administration of injectable preparations. They are supplied sterile and pyrogen – free and not to be re-sterilised or reused.

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

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

**Labeling:**

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

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

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

**Labeling for secondary packaging:****Secondary Package:**

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

- A description of the syringe including the capacity and the type of nozzle/ A description of the needle including the gauge and the nominal length
- Quantity of primary packages
- The word 'Sterile'
- That the syringe is for single use only
- The batch number
- The date (month and year) of sterilization
- Name and address of the manufacturer
- Date of Manufacture and Date of Expiry
- Information for handling, storage and transportation

**Quality Assurance:****Compliance:**

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

**Evidence:**

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

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

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

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

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

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

The supplier shall provide a copy of CE certificate.

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

**Packing:**

**Primary Package:**

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

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

**Paper-PVC Blister:**

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

**Secondary Package:**

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

**B. Inspection:**

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

**C. Testing::**

The Purchaser may cause independent laboratory testing to be performed as deemed necessary to

assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser's choice if suitably equipped and qualified to conduct quality assurance tests on the product.

**D. Labelling on Shipper Package:**

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

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

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

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

**E. Packing for Shipper Package:**

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

**F. Shelf Life of Artesunate Injection Kit:**

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

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

**G. Numbering of shipper packaging:**

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

**H. Qualification of the Manufacturer:**

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

**I. Recalls:**

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh

batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

**J. Model Inserts:**

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

**K. Colour Coding:**

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

**L. Bar Coding:**

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

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

Complete details on GS1 standards along with technical guidelines can be downloaded from [www.gs1india.org](http://www.gs1india.org) or [www.gs1.org](http://www.gs1.org)

**M. Documentation**

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

**Advance notice of arrival and advance shipping documentation:**

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

The documentation must include the following:

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

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

The pre-advice must contain the following information:

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



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

The following information shall be stated on the airway bill:

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

**N. Dispatch:**

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

<b>Schedule I</b>	<b>Schedule II</b>
Tab. ACT(Adult)- [SP + Artesunate]	Inj. Artesunate (60 mg)
Qty.- 10000	Qty.- 6000

Consignee: **IBD Store,  
36 Nirmal Chandra Street,  
Kolkata 700 013**

## **Section – V: Different Forms**

## Form 1: Check-List Form

[Please fill in and include with your Bid]

**All the documents submitted along with the bid should be self attested**

<b>Non statutory documents to be submitted under <u>My Space</u></b>				
Sl. No.	Activity	Yes/No/NA	Page No in the Bid	Remark
1	PAN Card of the bidder			
2	VAT Registration of the bidder			
3	CST Registration of the bidder			
4	WHO GMP and cGMP Certificate of the manufacturer			
5	Revised schedule M III Certificate			
6	ISO 13485 of the manufacturer			
7	CE Certificate of the Manufacturer			
8	Licence from Government/ Statutory Authority of the bidder as Applicable			
9	Factory Licence of the manufacturer			
10	Valid Drug Manufacturing Licence of the manufacturer			
11	Valid Drug distribution Licence in case of marketing organization			
12	Current registration as SSI (if any)			
13	Performance Statement Form (For the period of last three financial years) - Form 6 of Section V <b>To attach:</b> Documentary evidence (Client's certificate) in support of satisfactory completion of above orders.			
14	Income Tax returns and acknowledgement receipt for assessment year 2013-14			
15	VAT returns and acknowledgement receipt for assessment year 2013-14			
16	Legal declaration affirmed before a First Class Magistrate / Notary on non judicial stamp paper of Rs. 100/- for, a) Acceptance of Terms and Conditions of NIT and its Amendments and Addendums thereto. (As per Form 3 of Section V).  <i>Note: Technical evaluation of the bid will be taken up only after scrutiny of Form 3 (NIT Acceptance Form) duly notarized.</i>			
17	Legal declaration affirmed before a First Class Magistrate / Notary on non judicial stamp paper of Rs. 100/- for,  <b>No Adverse Report &amp; No Conviction Certificate (Form 7)</b>			
18	Manufacturer's Authorization (If applicable) as per Form 8 of Section V			
19	P/L & Balance sheet for last completed			

	calendar year/Financial year as applicable 2012-2013			
<b>BID - A</b>				
Sl. No.	Activity	Yes/No /NA	Page No in the Bid	Remark
20	Earnest Money Deposit (EMD)/ Bid Security in the form of Demand Draft (DD) or Bank Guarantee (BG). (* Tenderers to follow the format given in Form No. 4 of Section V, if EMD is submitted in the form of Bank Guarantee)			
<b>BID - B</b>				
Sl. No.	Activity	Yes/No/NA	Page No in the Bid	Remark
21	Name of the offered Item			
22	Certificate for 3 years market standing from a Chartered Accountant for the offered drugs/ medicine (having same specification as given in this bid document). A copy of valid manufacturing licence along with list of approved drugs valid for those 3 years should also be enclosed in support			
23	Copy of the Order/s and proof of payment for supplying items (in support of the eligibility criteria mention in <b>table 8.1 (b) - under Eligible Tenderers</b> ) to at least one national programme/ government (state/central) in India in last 5 years.			
24	Documentary evidence of manufacturing capability (in support of the eligibility criteria mention in <b>table under clause 8.9 - under Eligible Tenderers</b> )			
25	Test report of the manufacturer to be submitted by the Tenderer in respect of the batch for which sample has been submitted.			
26	Documentary evidence in regards to bio-compatibility of the device as per the requirements given in "Biological Evaluation of Medical Devices" IS 12572			
27	Certificate of analysis of Polydimethylsiloxane (Used for lubrication) Confirming to the requirements of IP			

**Form 2: APPLICATION FORMAT**

**To**  
**The Managing Director**  
West Bengal Medical Services Corporation Ltd.,  
Swasthya Bhawan,  
Sector – V, Salt Lake  
Kolkata – 700 091

**Sub: NIT for Supply of .....**

Ref:-

Sir,

Having examined the pre-qualification document (N.I.T.), I /we hereby submit all the necessary information and relevant documents for evaluation.

The application is made by me / us on behalf of.....  
in the capacity.....duly authorized to submit the bid.

The necessary evidence admissible by law in respect of authority assigned to us on behalf of the group of Firms for Application and for completion of the contract documents is attached herewith.

We are interested in supplying the materials mentioned in the Bill of Quantities.

We understand that:

- (a) Tender Committee of WBMSCL can amend the scope & value of the contract bid under this project.
- (b) Tender Committee of WBMSCL reserves the right to reject any application without assigning any reason ;

Date :-

**Signature of applicant including title  
and capacity in which application is made.**

### ***Form 3: NIT Acceptance Form***

Certified that all the terms and conditions of the NIT (mention NIT no.) and its Amendments and Addendum thereto are read and accepted without any modification or condition(s).

Authorized Signatory  
Company Seal

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*Note: Technical evaluation of the bid will be taken up only after scrutiny of form no. 3 (NIT Acceptance Form) duly notarized.*

**Form 4: Joint Venture Partner Information Form**

[The Tenderer shall fill in this Form in accordance with the instructions indicated below].

Date: [insert date (as day, month and year) of Bid Submission]

ITB No.: [insert number of bidding process]

Page \_\_\_\_\_ of \_\_\_\_\_ pages

1. Tenderer's Legal Name: [insert Tenderer's legal name]
2. JV's Party legal name: [insert JV's Party legal name]
3. JV's Party Country of Registration: [insert JV's Party country of registration]
4. JV's Party Year of Registration: [insert JV's Part year of registration]
5. JV's Party Legal Address in Country of Registration: [insert JV's Party legal address in country of registration]
6. JV's Party Authorized Representative Information Name: [insert name of JV's Party authorized representative] Address: [insert address of JV's Party authorized representative] Telephone/Fax numbers: [insert telephone/fax numbers of JV's Party authorized representative] Email Address: [insert email address of JV's Party authorized representative]
7. Attached are copies of original documents of:[check the box(es) of the attached original documents] Articles of Incorporation or Registration of firm named in 2, above, in accordance with Instructions to Tenderers. JV Agreement, or letter of intent to enter into such an Agreement, signed by the legally authorized signatories of all the parties
1. We undertake to get our Joint Venture registered with RBI and other statutory body in case of Award of contract and we agree that all future contracts will be in name of JV and all payment will be made in the account opened and operated by JV.

**Signature of JV partners**

### **Form 5: Bid Security (Bank Guarantee) Form**

**[To be submitted in a sealed envelope along with Technical Bid marked 'EMD' or 'Bid Security']**

*[Insert: No EMD or Bid Security is requested or The Bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.]*

\_\_\_\_\_  
*[Bank's Name, and Address of Issuing Branch or Office]*

**Beneficiary:** \_\_\_\_\_ *[Name and Address of WBMSCL]*

**Date:** \_\_\_\_\_

**BID GUARANTEE No.:** \_\_\_\_\_

We have been informed that *[name of the Tenderer]* (hereinafter called "the Tenderer") has submitted to you its bid dated (hereinafter called "the Bid") for the execution of *[name of contract]* under Invitation to Bid No. *[ITB number]* ("the ITB").

Furthermore, we understand that, according to your conditions, bids must be supported by a bid guarantee.

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

- (a) has withdrawn its Bid during the period of bid validity specified by the Tenderer in the Form of Bid; or
- (b) having been notified of the acceptance of its Bid by WBMSCL during the period of bid validity, (i) fails or refuses to execute the Contract Form; or (ii) fails or refuses to furnish the performance security, if required, in accordance with the Instructions to Tenderers.

This guarantee will expire: (a) if the Tenderer is the successful Tenderer, upon our receipt of copies of the contract signed by the Tenderer and the performance security issued to you upon the instruction of the Tenderer; or (b) if the Tenderer is not the successful Tenderer, upon the earlier of (i) our receipt of a copy of your notification to the Tenderer of the name of the successful Tenderer; or (ii) twenty-eight days after the expiration of the Tenderer's Bid.

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

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458.

\_\_\_\_\_  
*[Signature(s)]*



**Form 6: Performance Statement Form**

(for the period of last three years including Government supply)

Bid no: \_\_\_\_\_

Date of Opening: \_\_\_\_\_

Name of the Firm to which supply has been made

\_\_\_\_\_  
 Name of the Drug supplied \_\_\_\_\_ (Please provide separate statement for separate drugs)

Order placed by (Full address of purchaser)	Order no & date	Description & quantity of ordered items	Value of Order	Date of completion of Delivery		Remarks indicating reasons of late delivery, if any	Was the supplies of goods satisfactory
				As per Contract	Actual		

Signature and seal of the Tenderer

\_\_\_\_\_

Countersigned by and seal of Chartered Accountant -----

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To be attached: Documentary evidence (Client's certificate) in support of satisfactory completion of above orders.

***Form 7: No Adverse Report & No Conviction Certificate***

This is to certify that there is no adverse report against the ..... (Name of the Drug / Medicine) offered by ..... (Name of the Tenderer)

And

This is also to certify that there is no conviction report against the ..... (Name of the Manufacturer) for the ..... (Name of the offered Drug / Medicine) supplied to any State Government / Government of India.

Authorised Signatory of Tenderer\_\_\_\_\_

Name\_\_\_\_\_

Designation with stamp\_\_\_\_\_

Date\_\_\_\_\_

## **Form 8: Manufacturer's Authorization Form**

*[The Tenderer shall require the Manufacturer to fill in this Form in accordance with the instructions in the bid document. 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 Manufacture. Such certificate is not required where Manufacturer is the Tenderer.]*

Date:  
NIT No.:

To:  
MD, WBMSCL

### **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 Tenderer]* 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 with respect to the Goods offered by the above firm.

Authorised Signatory of the  
Manufacturer\_\_\_\_\_

Name\_\_\_\_\_

\_\_\_\_\_

Designation with  
stamp\_\_\_\_\_

Date\_\_\_\_\_

\_\_\_\_\_

## **Form 9: Performance Security**

*[Insert: No Performance Security shall be requested or the bank, as requested by the successful Bidder, shall fill in this form in accordance with the instructions indicated]*

Date: *[insert date (as day, month, and year) of Bid Submission]*  
ITB No. and title: *[insert no. and title of bidding process]*

Bank's Branch or Office: *[insert complete name of Guarantor]*

**Beneficiary:** *[insert legal name and address of WBMSCL]*

**PERFORMANCE GUARANTEE No.:** *[insert Performance Guarantee number]*

We have been informed that *[insert complete name of Supplier]* (hereinafter called "the Supplier") has entered into Contract No. *[insert number]* dated *[insert day and month]*, *[insert year]* with you, for the supply of *[description of Goods and related Services]* (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 Supplier, we hereby irrevocably undertake to pay you any sum(s) not exceeding *[insert amount(s)<sup>1</sup> in figures and words]* upon receipt by us of your first demand in writing declaring the Supplier to be in default under the Contract, without cavil or argument, or your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

This Guarantee shall expire no later than the *[insert number]* day of *[insert month]* *[insert year]*,<sup>2</sup> and any demand for payment under it must be received by us at this office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458, except that subparagraph (ii) of Sub-article 20(a) is hereby excluded.

*[signatures of authorized representatives of the bank and the Supplier]*

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<sup>1</sup> *The Bank shall insert the amount(s) specified in the SCG and denominated, as specified in the SCG, either in the currency(ies) of the Contract or a freely convertible currency acceptable to WBMSCL.*

<sup>2</sup> *Dates established in accordance with Clause 12 of the General Conditions of Contract ("GCG"). WBMSCL should note that in the event of an extension of the time to perform the Contract, WBMSCL would need to request an extension of this Guarantee from the Bank. Such request must be in writing and must be made prior to the expiration date established in the Guarantee. In preparing this Guarantee, WBMSCL might consider adding the following text to the Form, at the end of the penultimate paragraph: "We agree to a one-time extension of this Guarantee for a period not to exceed [six months] [one year], in response to WBMSCL's written request for such extension, such request to be presented to us before the expiry of the Guarantee."*

## **General guidance for e-Tendering**

Instructions/ Guidelines for tenders for electronic submission of the tenders online have been annexed for assisting the prospective Tenderers to participate in e-Tendering.

1. Registration of Tenderers:  
Any Tenderer willing to take part in the process of e-Tendering will have to be enrolled & registered with the Government e-Procurement system, through logging on to <https://etender.wb.nic.in> . The prospective Tenderer is to click on the link for e-Tendering site as given on the web portal.
2. Digital Signature certificate (DSC)  
Each Tenderer is required to obtain a class-II or Class-III Digital Signature Certificate(DSC) from NIC for submission of tenders, from the approved service provider of the National Information's Centre(NIC) on payment of requisite amount.
3. The Tenderer can search & download NIT & Tender Documents electronically from computer once he logs on to the website using the Digital Signature Certificate. This is the only mode of collection of Tender Documents.
4. Participation in more than one item :  
A prospective Tenderer shall be allowed to offer rate as per his or her choice subject to fulfillment of conditions laid down hereinabove and conforming to his production capacity to be laid down in the tender paper.
5. Submission of Tenders.  
General process of submission, Tenders are to be submitted through online to the website at a time for each work, one in Technical Proposal & the other is Financial Proposal before the prescribed date & time using the Digital Signature Certificate (DSC) the documents are to be uploaded virus scanned copy duly Digitally Signed. The documents will get encrypted (transformed into non readable formats).
6. Physical verification of samples to be made by the expert committee after evaluating Technical proposal.