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BID DOCUMENT FOR RATE CONTRACT AND SUPPLY OF DRUGS/ MEDICAL DEVICES/ CONSUMABLES FOR DIFFERENT HEALTHCARE FACILITIES OF STATE OF BIHAR IN VIEW OF PANDEMIC EMERGENCY SITUATION PREVAILING DUE TO NOVEL CORONA VIRUS (COVID-19) OUTBREAK FOR THE YEAR 2020-2022.

(Tender Reference No. BMSIC/ MEDICAL DEVICES/ CONSUMABLES/ 20-01)

Bihar Medical Services and Infrastructure Corporation Limited (BMSICL)

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BIHAR MEDICAL SERVICES AND INFRASTRUCTURE CORPORATION LIMITED

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1. INTRODUCTION

Managing Director, Bihar Medical Services and Infrastructure Corporation Limited (Government of Bihar), (hereinafter referred as Tender Inviting Authority) invites Tender for the supply of DRUGS, MEDICAL DEVICES/ CONSUMABLES related to COVID-19 for various healthcare facilities of state of Bihar. This tender is an e-tender and only online bid submission is possible.

2. TENDERING SYSTEM

The Bids are to be submitted in two Parts i.e.

I. Technical Bid

II. Financial Bid / Price Bid

The TECHNICAL BID shall contain the complete technical details of the firm and the documents to provide the eligibility and competency of the bidder and shall be submitted online only in the manner prescribed in Bid document.

The documents like Tender Document fee and EMD shall be submitted before the specified schedule at the office of BMSICL super scribed, "Tender Document Fee & Earnest Money Deposit for Tender Reference No. **BMSIC/ MEDICAL DEVICES/ CONSUMABLES/ 20-01** dated **22/05/2020** for the procurement MEDICAL DEVICES/CONSUMABLES for the year **2020-22**". However hard copy of uploaded tender shall be provided by the bidder firm alongwith the mandatory tender document fee and EMD for evaluation purpose only. This hard copy shall in no case substitute/modify the provisions of e-tender system.

a) The **Financial Bid/ Price Bid** in the prescribed Performa shall be submitted online only. **The price shall be quoted on basic units (Viz per piece/ per test/ per pair/**

per bottle etc.) mentioned in Financial Bid / Price Bid format and not in respect of any other supply units.

b) The Tender has been called for in the generic names of DRUGS, MEDICAL DEVICES/ CONSUMABLE. The bidders should quote the rates for the DRUGS, MEDICAL DEVICES/ CONSUMABLES in generic names. The products offered shall comply with the tender specifications given in **Annexure-I.**

c) Rates (inclusive of packing & forwarding, Sales Tax, Excise Duty, Customs duty, transportation, handling, loading & unloading, insurance and any incidental charges) should be quoted for each DRUGS, MEDICAL DEVICES/ CONSUMABLES "on door delivery basis" in the format given in price bid. Conditional bid shall not be accepted. **The delivery destination (On F O R basis) shall be the different warehouses of BMSICL across the state of Bihar.**

d) The price quoted by the bidders must not exceed the ceiling price as fixed by **NPPA (National Pharmaceutical Pricing Authority)** as per the provisions of "**Drugs Price Control Order**" and the quoted rate should be at least 20% less than its MRP (as applicable).

e) The bidder shall allow inspection of the factory at any time by an Expert/Official or by a team of Experts/Officials of the Tender Inviting Authority. The bidder shall extend all assistance and cooperation to the team to enable to inspect the manufacturing unit, quality control measures adopted etc., in the manufacturing process of the MEDICAL DEVICES/CONSUMABLES.

3. Minimum Eligibility Criteria (TECHNICAL BID -COVER "A")

Minimum Eligibility criteria along with list of documents to be submitted in Cover 'A'. Bidders should meet the following criteria to be eligible for bidding and relevant papers/documents must be submitted by them in their technical bid (Cover-'A') in support of their eligibility for the tender.

a) Tender Fee (Non –Refundable) of Rs 10,000/- in form of Demand Draft drawn in Favor of "**Managing Director, Bihar Medical Services and Infrastructure Corporation Limited**" payable at Patna. This fee is payable only once for one tender irrespective of items contained therein.

b) The bidder is required to submit Earnest Money Deposit in the form of Demand Draft/ Bank Guarantee drawn in favor of Managing Director, **Bihar Medical Services and Infrastructure Corporation Limited issued** from any Scheduled/ Nationalized bank payable at **Patna** as per following table: -

S.N.	No. of items quoted	EMD Amount
1	Upto 5 items	Rs 1,00,000/- (One Lakh only)
2	For 6 to 10 items	Rs 2,00,000/- (Two Lakh only)
3.	For 11 to 15 items	Rs 3,00,000/- (Three Lakh only)
4.	For 15 to 20 items	Rs 4,00,000/- (Four Lakh only)
5.	More than 20 items	Rs 5,00,000/- (Five Lakh only)

c) Documentary evidence of the constitution of the company/firm such as Memorandum and Articles of Association, Partnership Deed etc. should be submitted with details of the Name, Address, Telephone Number, Fax Number, E-mail address of the firm and of the Managing Director / Partners / Proprietor should be submitted.

d) The details of Bidder Name, Address, Telephone Number, Fax Number, e-mail address of the bidder and of the Managing Director / Partners / Proprietor should be submitted in **Annexure-V**.

e) Power of Attorney or Resolution of the Board by which the authorized signatory has been authorized by the bidder firm to sign the documents should be submitted.

f) Bidders must have: -

(I) In case of manufacturer, the bidder firm must have a valid manufacturing license or duly acknowledged renewal application with old license issued by the State licensing authority/Central licensing approving authority under Drugs & Cosmetics (D&C) Rules 1945/ Medical Devices Rules 2017/ license issued by industry department or concerned government department, as applicable.

- Approved product list as per the license issued for quoted MEDICAL DEVICES/CONSUMABLES as Drugs & Cosmetics (D&C) Rules 1945/ Medical Devices Rules 2017 where ever applicable.
- Manufacturing License along with approved product list must be valid till the last date of the submission of tender (As Applicable).

- Valid Pollution Control Clearance Certificate in accordance with Water [Prevention and control of Pollution] Act, 1974 & Air [Prevention and control of Pollution] Act, 1981 and Hazardous Wastes (Management, Handling & Trans Boundary Movement) Rules 2008 (Self Attested Copy of Certificate to be enclosed) (as applicable).

  Bidders shall submit self-attested copies of required manufacturing license and approved product list in support of above-mentioned condition and they are required to specify the quoted products in their approved product list by highlighting it. (As Applicable)

(II) In case of Importer, the bidder (importer) firm must have valid import license of the quoted product. All quoted products should be accompanied by their invoices, statement and import license showing that the quoted product is being imported and sold in India by the bidder (Importer firm). Import license must be valid on the last date of submission of tender.

(III) In case of Non-drug item(s) where neither the Drugs & Cosmetics (D&C) Act 1945 nor the Medical Devices Rules 2017 is applicable the bidder must have a manufacturing license/import export certificate (IEC) with an undertaking/Self declaration as per **Annexure-VIII** that the item(s) quoted by the bidder is/are non-drug item(s) i.e. neither covered under D & C Act nor under Medical Devices Rules 2017.

g) Non-Conviction Certificate (NCC) issued by the concerned Licensing Authority from Drugs Control Administration/ Concerned Government Department of the state should be submitted (As Applicable). It should be not more than one year old. Self-attested copies are to be submitted.

h) WHO-GMP/GMP (Good Manufacturing Practice) as per revised Schedule-'M'/COPP Certificate of the manufacturing unit issued by the Licensing Authority/ Drugs Control Department/BIS/ISI certificate issued from the concerned department (As Applicable). The GMP certificate should remain valid till the last date of submission of tender. Self-attested copies are to be submitted.

Explanation- Generally the GMP Certificate issued for one-year validity. Hence the provision that it should not be older than one year from the last date of submission of tender implies mutatis mutandis that the GMP certificate should remain valid till the last date of

submission of tender.

i) Maximum Batch Production Capacity Certificate (section wise) issued by concerned Licensing Authority from Drugs Control Department/ Concerned Government Department high lighting the quoted product section (As Applicable). Self-attested copies are to be submitted. In case of Importer, an affidavit (with Stamp) sworn before first class magistrate/ Notary stating the batch production capacity of the firm and also that the **said production (Importing) capacity** shall be adequate for requirement laid in NIT. Importers will have also to submit Invoices/Evidence of import in items of said product with quantity details. The onus lies on the bidder to provide its production capacity through the production capacity (Self Declaration) to be submitted by the bidder as contained in Annexure-IX. This statement shall be in addition to the Production Capacity Certificate (section wise) obtained by the bidder from the concerned competent authority.

j) Copies of the Audited Balance Sheet and Profit and Loss statement showing details of their annual average turnover not less than **5 Crores** for any three of the last four consecutive financial years (Auditor/CA certificate of turnover will not be accepted). Self-attested copies are to be submitted.

k) Copy of Income Tax Return for any three of last four consecutive Assessment years should be submitted (Self Attested copies).

l) The tenderer should give an affidavit sworn before a First Class Magistrate/ Notary stating that the firm & its quoted product is not black listed currently (as on the date of submission of the tender) by Central Government/ Central Government agencies/any State Government or any of the State Government agencies/ or any Drug procurement agencies or by BMSICL as per **Annexure-II.**

m) List of items quoted in prescribed format as per **Annexure-III** duly signed**.**

n) Copy of PAN Card of the bidder firm should be submitted (self-attested).

o) Copy of certificate of valid **GST registration** of the bidder firm should be submitted (self-attested).

Note: -

(i) Technical evaluation of the Bid will be done on the basis of the above mentioned criteria and documents mentioned at S.N. 3 (TECHNICAL BID- COVER 'A') in Mandatory Documents Link present in the web portal of the www.eproc.bihar.gov.in, failing which the bid will not be considered for technical evaluation.

(ii) Hard copy of tender documents uploaded shall be submitted along with the tender fee and EMD as on or before the last day of submission of tender for purely evaluation purposes. However, the submission of hard copy of uploaded tender document submitted does not substitute/modify the provisions of e-tendering system.

(iii) The technical evaluation shall be done only on the basis of documents/ papers submitted by the bidder on www.eproc.bihar.gov.in.

4. FINANCIAL BID / PRICE BID

a) The Financial Bid/ Price Bid will contain only the "Price Bid Form" and every bidder shall submit their rates in the prescribed format attached to the Bid document. The price bid submitted in any other format will be treated as non-responsive.

b) The Financial Bid/ Price Bid excel file shall be downloaded from the e-tender portal and quote the prices in the prescribed format before uploading it. The bidders shall not rename the price bid files downloaded.

c) The bidder shall quote prices in all necessary fields in the available format. All blue areas of financial bid excel sheet shall be filled by the bidder. The white areas of financial bid sheet shall not be modified/ edited by the bidder.

d) The rate quoted shall be on per unit **(Viz. per piece/ per test/ per pair/ per bottle etc.)** inclusive of all taxes viz., as may be applicable, insurance, freight, handling charges at various heads etc., excluding GST as mentioned in above clause 2(c).

5. GENERAL CONDITIONS

a) Tender bid is invited directly from **Manufacturers/ Loan Licensees or Direct Importers only.** Distributors/agents/contract manufacturers are not eligible to participate in the tender.

b) A complete set of tender documents may be purchased online @ www.eproc.bihar.gov.in by any interested eligible person of the tenderer upon payment of a non- refundable fee of Rs.10,000/- in the form of Demand Draft drawn in favor of "**Managing Director, Bihar Medical Services and Infrastructure Corporation Limited**" payable at Patna and the same must be submitted before the specified date and time at the office of BMSICL. In no case, the tender cost should be mixed with the EMD amount.

c) All tenders must be accompanied with Earnest Money Deposit as specified in the tender document.

d) Pre-Bid meeting shall be held as per Notice Inviting Tender. But in case the lockdown like situation persists or in view of necessity of physical distancing the pre-Bid meeting may be dispensed with and instead online suggestions/queries through e-mail to **bmsicl.covid19@gmail.com** may be invited upto the 7th day after the publication of the NIT and after addressing the queries/suggestions properly, suitable corrigendum/addendum may be issued with wide publicity on the website of **www.eproc.bihar.gov.in** as well as on the website of BMSICL.

e) At any time prior to the last date of submission of tender, Tender Inviting Authority may, for any reason, whether at their initiative or in response to a clarification requested by a prospective bidder, can modify the condition of tender documents by an amendment.

f) The detailed list of the required DRUGS, MEDICAL DEVICES/ CONSUMABLES in view of the pandemic COVID-19, is given in **Annexure-I**. **The required quantity may vary in accordance with the actual need as warranted by the situation.**

g) The Tenderers should quote the rates for the generic products only. Each product should be as per specifications given in **Annexure-I.**

h) All items to be supplied need to be accompanied with certificate of analysis from National/ International Organizations/ Labs indicating conformity to standards.

i) Manufacturers located in Bihar will be guided by **Bihar Industrial Investment Policy, 2016 for promoting industrial development in the State** for the Technical Qualification, EMD and Security Deposit. Copy of the said policy may be seen on the website http://industries.bih.nic.in/

j) The certificates/ reports / annexures submitted with the bid document should be self-attested by the authorized signatory of the firm with official seal, wherever required.

k) Affidavit declaration regarding acceptance of tender conditions to be submitted by the bidding firm as per **Annexure-IV.**

l) Filled check list as per given **Annexure-VI to be submitted at the time of uploading the bid**.

m) Withdrawal or non-compliance of agreed terms and conditions after the execution of agreement will lead to invoking of penal provisions and may also lead to blacklisting of the successful bidder.

n) Validity of Rate Contract: - The rate contract shall remain valid for **Two years** from the date of signing of the rate contract. The validity of contract may be extended with mutual consent for some specified period upto a maximum period of one year by BMSICL, if necessary.

6. EARNEST MONEY DEPOSIT

a) The Earnest Money Deposit shall be as mentioned in clause 3(b) of NIT, which shall be paid in the form of Demand Draft/ Bank Guarantee, favoring Managing Director, Bihar Medical Services and Infrastructure Corporation Limited issued from any Scheduled/ Nationalized Bank and payable at Patna.

b) Non-payment of Tender cost and EMD (except in cases where payment of Tender Cost and EMD are specifically exempted) will result in summarily rejection of the bid.

c) EMD of unsuccessful bidders will be discharged/ refunded to the bidders account after finalizing the tender.

d) EMD of the successful bidders will be returned on signing the contract & furnishing of required Performance Security Deposit.

e) The Earnest Money Deposit of the Tender will be forfeited without further notice if:

- **i.** Any bidder withdraws his offer within the bid validity period before finalization of the tender.
- **ii.** On refusal of the bidder to enter into a contract agreement after the award of contract/ Letter of Intent.
- **iii.** If the bidder fails to produce hard copies of the documents as specified or to sign the contract after issuance of offer letter/ Letter of Intent.
- **iv.** If the bidder fails to furnish security deposit after issuance of offer letter/ Letter of Intent.

7. GUIDELINES FOR THE PREPARATION OF TENDER

a) The bidder shall bear all costs associated with the preparation and submission of its bid and Tender Inviting Authority will in no case be responsible or liable for these costs, regardless of the conduct or outcome of the bidding process.

b) **Language of Bid: -** The Bid prepared by the bidder and all correspondence and documents relating to the bid exchanged by the bidder and the Tender Inviting Authority, shall be in English language, Supporting documents furnished by the bidder may be in other languages provided they are accompanied by an authenticated (by the authority concerned) accurate translation of the relevant passages in the English language in which case, for purposes of interpretation of the Bid, the English translation shall alone govern. Failure to submit authentic translation of documents would result in rejection of bids. No bid can be partly in one language and partly in another language.

c) Power of Attorney or Resolution of the Board by which the authorized signatory has been authorized by the bidder firm should sign the documents in cases where person other than the Managing Director/ Managing Partner or sole Proprietor signs the document.

8. PERIOD OF VALIDITY OF TENDER

a) The tender must remain valid for minimum 180 days from the date of opening of Technical Bid.

b) Prior to the expiration of the bid validity the Tender Inviting Authority may extend the bid validity for further period with mutual consent of the bidder.

c) The bidder who has extended the bid validity is not required or permitted to modify its bid.

d) The bidder cannot withdraw the bid within the bid validity period.

9. AMENDMENT OF TENDER DOCUMENTS

Bidders/ Prospective bidders are advised to visit the website of the Tender Inviting Authority/ website of e-tender for any information/ general notices/ amendments to Tender Document etc. on a day to day basis till the tender is concluded.

10. METHOD OF SUBMISSION OF TENDER

a) The Tender shall be submitted online only. Bidders shall upload all necessary Technical bid documents into the e-tender portal.

b) Both Technical Bid and Price Bid are to be submitted concurrently duly digitally signed in the website at **"www.eprocbihar.gov.in".**

c) If a particular document/ Certificate to be uploaded as specified in bid, is not applicable for a bidder, the bidder shall attach a scanned copy of declaration in the letter head stating that the specific document is not applicable/ exempted for the bidder in connection to this tender.

d) Bids along with necessary online payments (bid processing fee) must be submitted through e-procurement portal www.eproc.bihar.gov.in before the date & time specified in the bid document/ NIT /Tendering Authority does not take any responsibility for the delay/ Non submission of tender/ Non reconciliation of online payment (bid processing fee) cost due to non-availability of internet connection, network traffic / holidays or any other reason.

e) For support related to e-Tendering process, bidders may contact at following address "e-Procurement HELP DESK, 1st Floor, M/22, Bank of India Building, Road No. -

25, Shree Krishna Nagar, Patna- 800001. Phone No. 0612-2523006, Mob. No. 7542028164 or may visit the link "Vendor info" at www.eproc.bihar.gov.in and also inform in this regard to BMSICL.

f) Once the bid has been uploaded on the web portal www.eproc.bihar.gov.in, the bidder has to make sure that he has uploaded the files in the correct format and the bidder has to download the uploaded files from his own end and has to check whether the files uploaded is in proper format or not. No corrupted files have to be uploaded.

11. DEADLINE FOR SUBMISSION OF TENDER

The electronic bids of the bidders who have submitted their digitally signed bids within the stipulated time, as per the tender schedule alone will be accepted by the system.

12. MODIFICATION AND WITHDRAWAL OF BIDS

a) The bidder may modify or withdraw his bid after the bid submission before last time and date of submission of online Technical Bid.

b) No bid will be allowed to be withdrawn after the last date & time of submission of online Technical Bids.

13. OPENING OF TENDER

a) The opening of the Technical Bid and the Price Bid will be done online as specified. The date of technical bid opening is only published in advance. The date of opening of price bid will be announced only after the opening and evaluation of Technical bid. The date and time of price bid opening will be published on the website of the Corporation.

b) The bidder shall be solely responsible for properly super scribing and sealing the envelope submitting DD/ BG for EMD.

14. EVALUATION OF TENDER

a) Technical evaluation of the Bid will be done on the basis of criteria and documents mentioned in S.N. 3 (TECHNICAL BID-COVER A) in Mandatory Documents Link present in the web portal of the www.eproc.bihar.gov.in.

b) Bids of firms who have furnished all the required documents for each of the product quoted will be considered.

c) Final rate list of L1 bidders will be published on the website of the Corporation.

d) If at any stage, it is found that the tender has been successfully obtained by the bidder by submitting forged/ fabricated certificates/ documents/ licenses and/or by concealing the fact about blacklisting/ debarring/ de-registration of the firm by Govt. of India/ Suspension/ Cancellation/ non-renewal of the manufacturing license of the bidder firm, the tender bid/ rate contract may be rejected/ terminated and suitable punitive/ legal action may be taken against the firm.

e) In event of financial bid opening, due to provisions/ compulsion of e-tendering system if complete quoted product list of financial bids of a bidder is opened then only those financial bids of quoted product shall be considered of whose technical bid has been found eligible by the Technical Evaluation Committee.

15. **INSPECTION OF MANUFACTURING FACILITIES**

a) Inspections of the production and related facilities of bidders/ suppliers will be done as per the discretion of the Tender Inviting Authority. Such inspection may be at any stage before or after acceptance of the Bid or Award of Contract.

b) Copy of one full set of the documents submitted for the bid should be made available at the time of inspection.

c) Originals of all the documents uploaded/ submitted in the Technical Bids should be produced for verification during Site inspection and Physical Verification.

16. ACCEPTANCE /REJECTION OF BIDS

The Tender Inviting Authority reserves the right to accept/ reject/ cancel or defers the Tender submitted for any or all items.

17. AWARD OF CONTRACT

a) The contract will be awarded to the lowest evaluated responsive bidder qualifying to the final round after Technical and Price Bid evaluation subject to the reservations and preferences of the state.

b) Letter of Intent: The Tender Inviting Authority shall issue Letter of Intent (LOI) to the lowest responsive bidder in respect of the Drugs, Medical Devices/ Consumables

selected. Communication by e-mail / fax / letter will be deemed as valid communication.

c) Signing of Contract:

i. The successful bidder, upon receipt of the Letter of intent, shall communicate the acceptance of the same to the BMSICL and shall furnish the required documents asked if any, along with the agreement in the prescribed format as forwarded along with LOI on a Non-Judicial stamp paper of value of **Rs.1000/-** (stamp duty to be paid by the bidder). 10% of Performance Security shall be deducted from every running bill paid to the successful bidders, however this amount may be release after submission of Performance Bank Guarantee.

ii. The bidder shall not, at any time, assign, sub-let or make over the contract or the benefit thereof or any part thereof to any person or persons what so ever. Such practices will be deemed as fraudulent practices and also as breach of the terms of contract and shall invite punitive action.

18. SECURITY DEPOSIT/ PERFORMANCE GUARANTEE

a) There will be a Security Deposit amounting to 10% (in Indian rupees) of total value of ordered item/ items. **The said Security Deposit shall be deducted from every running bill paid to the successful bidders, which will be returned after submission of Performance bank Guarantee of the same value.**

b) Tender Inviting Authority will release the Security Deposit without any interest to the bidder on successful completion of the bidder's all contractual obligations.

19. PURCHASE PROCEDURES

a) As per the conditions outlined in the Procurement manual (duly approved by the Health Department, Government of Bihar) and in the best interest of people of Bihar in order to ensure uninterrupted supplies in the state, it is decided to have more than one source of supply specially in case of procurement of medicines/ medical devices/ consumables considering their criticality and vitality. The following policy shall be adopted on splitting of quantities.

Where situation so warrants, tender quantity of one or all the item(s) may be split in favour of one or more firms on merit of each case and with the approval of TIA after giving due regard to the following: -

i) Vital/ Critical nature of the item.

ii) Quantity to be procured.

iii) Delivery requirements.

iv) Capacity of Firms in the zone of consideration and

v) Past performance of Firms.

The financial evaluation committee shall make counter offers thereafter to L2 and L3 at the rates offered/ quoted by L1 and the entire quantity shall be split among the L1 and agreed L1 bidders. The counter offer shall not be extended beyond L3 Bidder.

If both L2 and L3 bidder agree to match the L1 rate, then the splitting will depend on Percentage difference between the L1 and L2 offered rates (Quoted Price).

Price Difference between L1 and L2	**Quantity distribution ratio between L1, L2, L3**
Upto 3%	60:20:20
More than 3% and upto 5%	65:17.5:17.5
More than 5%	70:15:15

In case, either of L2 or L3 only accepts the counter offer then the splitting shall be done according to the following table.

Price Difference between L1 and L2/L3	**Quantity distribution ratio between L1 and L2/L3**
Upto 3%	60:40
More than 3% and upto 5%	65:35
More than 5%	70:30

In case both L2 and L3 bidder disagree to match the L1 declared price and refuse to accept the counter offer, then 100% quantity shall be ordered to L1 only.

If on Financial evaluation two or more bidders are found to have L1 rates, then the total quantity shall be split in equal proportion (e.g.- if two bidders are found L1 then quantities shall be split in 50:50 proportion). In such a situation, offer will not be extended to L2 & L3 to match the price.

b) The supplier shall supply the DRUGS, MEDICAL DEVICES/ CONSUMABLES required by the Tender Inviting Authority at the destination(s) within the period stipulated in the purchase order.

c) The supplier shall supply the item(s) at the specified destination along with **original invoice**, **Test reports of finished products for every batch, Delivery Challan** and other relevant documents at the destinations. Any supply without the above documents will not be accepted and the said supply will be accepted only on the date of submission of the required document.

d) It is the duty of the supplier to supply products at the destinations mentioned in the Purchase Order and supply shall confirm to the conditions mentioned in the provisions of NIT, rate contract and directives of BMSICL.

e) Subject to the conditions mentioned in the Purchase Order, Tender Document, Agreement executed by the supplier, the Supplier is entitled for the payment against supply. In case of any discrepancy in levy of Liquidated Damages, Penalty, Unexecuted Fine, Short Passing of Bills, such discrepancy shall be intimated within 15 days from the date of receipt of payment, failing which BMSICL will not entertain any claim thereafter.

20. SUPPLY CONDITIONS

a) The products supplied by the successful bidder shall be of the Standard Quality and shall comply with the specifications, stipulations and conditions specified under Drugs and Cosmetics Act and Rules thereunder (as applicable) and also should confirm to the Terms and Conditions laid down in the NIT and Rate Contract/ Agreement.

b) The supplier shall supply the DRUGS, MEDICAL DEVICES/CONSUMABLE required by the Tender Inviting Authority at the destination(s) within the period stipulated in the purchase order.

c) Different purchase orders shall be billed separately. Under no condition single invoice for different Purchase Order shall be admitted.

d) The supply schedule is mentioned in clause 21 of this bid document.

e) Leaked, soiled, broken containers with damaged labels shall not be accepted.

f) The supplied products must have 75% **of shelf life period**. The bidder shall submit the certificate of analysis from an NABL Accredited Drug Testing Laboratory/Central Drug Laboratory/In House Quality Control Laboratory with necessary protocols for every batch of items supplied along with the consignment (as applicable).

g) The bidder shall submit the certificate of analysis from an NABL Accredited Drug Testing Laboratory/ Central Drug Laboratory/ In House Quality Control Laboratory with necessary protocols for every batch of items supplied along with the consignment (as applicable).

For the supply of Personal Protection Equipment (PPE) Kits, the Fabric, Garment/Coverall, Seam and feet/Shoe cover should pass Synthetic Blood Penetration test at South India Textile Research Association (SITRA), Coimbatore or Defence Research and Development Establishment (DRDE), Laboratories. Manufactures/suppliers submitting the pass certificate as above shall only be considered as qualified, as per Textile Ministry, GoI Notification No-F.No.-8/4/2020-R&D, dated 22-04-2020 as revised from time to time.

h) The supplier shall, after supply of products at the specified destinations, submit Invoice and other relevant documents etc., at the Head Office, BMSICL claiming payment for the supply made. Detailed provisions mentioned in clause 25 (d).

i) The supplier shall supply the DRUGS, MEDICAL DEVICES/CONSUMABLE at the specified destination(s) and submit the copy of invoice, copy of the Purchase order, Test Report, Delivery Challan and other relevant documents at the destinations. For the purpose of this invoice shall specify the generic name of the DRUGS, MEDICAL DEVICES/CONSUMABLE as tendered together with brand name if any. Where more than one batch of the DRUGS, MEDICAL DEVICES/CONSUMABLE is supplied under one invoice, the quantities of each batch supplied shall be clearly specified. The date of manufacture, the date of expiry of each batch shall be specified. The quantity supplied shall be in terms of the units mentioned in the tender document. The suppliers are cautioned that any

variation in the description of product in the invoice/ analysis report and actual supplies will be considered as improper invoicing and will dealt with accordingly.

j) The bidder will be responsible for any shortages/ damage at the time of receipt in Warehouse. Tender Inviting Authority shall not be responsible for the excess quantity of drug received, for which no order is placed. In such cases, the bidder shall take back the excess quantity supplied at his own expenses within fifteen days from the date of such intimation. Unclaimed excess supplies will be disposed of by the Tender Inviting Authority at its discretion and demurrage of **Rs.100/-per box per day** will be levied for the retained period.

k) In the event of DRUGS, MEDICAL DEVICES/CONSUMABLE not being utilized within their shelf life period, the firm shall replace unspent/ unused/ expired stock by fresh stock with shelf life as per the clause 20(f) without any extra cost unconditionally.

21.

SUMMARY OF SCHEDULE			
Sl. No.	***Activity***	**:**	**Time Limit**
1	**Schedule of Dispatch Details**		
	0th day	**:**	Letter of Intent (LOI)/Purchase Order or both
	Within 7 days of LOI	**:**	The supplier shall submit agreement, the hard- copies of the documents submitted and other documents specified, copy of LOI duly signed and sealed on all pages in token of acceptance.
	Within 3 days of PO	**:**	The supplier shall furnish confirmed dispatch schedule. If the confirmed dispatch schedule is not received on or before the specified period, the purchase order is liable to be cancelled and arrangement for alternate purchases will be done at the risk and cost of the supplier.
2	***Schedule of purchase order and Supply of***	**:**	The schedule of supply of MEDICAL DEVICES/ CONSUMABLE will be as follows.

	DRUGS, MEDICAL DEVICES/ CONSUMABLE	**:**	No of days from Purchase Order	% of the ordered quantity to be supplied in each warehouse.	Penalty for default supply
		:	Within 15 Days	50%	***After 25th days penalty will be @ 1 % of value of unexecuted supply order per day subject to a maximum of 20% penalty.**
			Within 25 Days	100%	
			Within 35 Days	*****Unexecuted Supply	
			On the 35th day from the date of issue of PO at 1700 Hrs. the PO stands cancelled.		

*** NOTE- The supply conditions may be increased or decreased keeping in mind to favour General patients of state may be decided by the Managing Director, BMSICL from time to time.**

22. LOGOGRAMS

a) FOR GOVERNMENT SUPPLY – NOT FOR SALE" shall appear in primary, secondary and tertiary packing of all products which will be bolder than those already printed on the label.

b) All the **DRUGS, MEDICAL DEVICES/CONSUMABLES** Items have to be supplied in standard pack size with printed logogram of proportionate size and shall also confirm to **Schedule P1 of the Drugs & Cosmetics Act & Rules** (As applicable)**.** Affixing of stickers and rubber stamps shall not be accepted. *Affixing of stickers will be permitted on request only in case of imported products on merits (As Applicable).*

c) Supply of items without the logogram and/or "BIHAR GOVERNMENT SUPPLY – NOT FOR SALE" shall not be accepted.

23. PACKING

a) 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 NIT. The packing shall be sufficient to withstand without limitation, rough handling during transit and exposure to extreme temperatures, humidity, salt and precipitation during transit and open storage. The packing, marking and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided.

b) The cap of the bottle shall not bear the name of the manufacturer.

c) Leaked, soiled, broken containers with improper packaging, damaged labels shall not be accounted for the purpose of supply.

d) Printed Packing Slip containing full details about the contents like Quantity, Batch No., Expiry date etc. should be pasted on every parcel.

e) As far as possible supply should be made from single or minimum number of batches. Separate batches should be packed in separate pack.

f) Labelling on MEDICAL DEVICES/CONSUMABLES boxes/ cartons and other items should be clear and legible. Labels should be well stuck on to the container. If not, the supply may be rejected.

g) Loose packing shall not be accepted.

h) The products shall also be supplied with bar coding conditions. (For details visit website **www.gs1india.org** .

i) The packings/labels of two different products of a same supplier should be clearly distinct from each other.

24. QUALITY TESTING & QUALITY CONTROL

a) All the batches of the MEDICAL DEVICES/ CONSUMABLES supplied shall be supported by test/ analysis reports furnished by independent NABL Accredited Drug Testing Laboratory/Central Drug Testing Laboratory/ South India Textile Research Association (SITRA), Coimbatore/ Defence Research and Development Establishment (DRDE) Laboratories/ In House Quality Control Laboratory (As applicable). The TIA has the right to get the MEDICAL DEVICES/ CONSUMABLES tested at the laboratories of

his choice for further verification, from BMSICL empanelled laboratories or any government laboratory.

b) The supplier shall have to furnish evidence of the basis for expiration dating and other stability data concerning the commercial final package on request made by BMSICL. In case of any adverse report in the field, the BMR/BPR for the particular batch of the product(s) supplied shall have to be produced as and when demanded.

c) Random samples of any or all supplied batches may be chosen at the point of supply or distribution/ storage points for testing. The samples may be sent to different BMSICL empanelled laboratories.

d) A flat 2% of total bill amount shall be deducted from the bills of the supplies product toward testing and Handling charges of product from the suppliers as amended.

e) The product shall be of standard quality throughout the shelf life period of the item. Samples can be drawn for quality testing periodically throughout the shelf life period. If the sample is declared to be "NOT OF STANDARD QUALITY" or spurious or adulterated or misbranded, such batch/ batches will be deemed to be rejected goods and action will be taken as per tender clause.

f) If the product / sample fails in quality test, every failed batch shall be taken back by the supplier at their own cost and BMSICL shall not be responsible for any damage during this period.

g) If a sample is found as Not of Standard Quality (NSQ) by the Tender Inviting Authority, the distribution of NSQ batch will be frozen. The bidder will be liable for appropriate action as per the tender conditions and also for other legal actions under the Drugs & Cosmetics Act & Rules (As applicable). The Tender Inviting Authority, at his discretion may terminate the Contract and in case of such termination, the supplier shall be liable for all losses sustained by the Tender Inviting Authority, which may be recovered from the Security Deposit made by the Supplier and/ or any other money due or becoming due to him. In the event of such amounts being insufficient, the balance may be recovered from the Supplier as per the provisions of Law.

25. PAYMENT PROVISIONS

a) No advance payments towards costs of product will be made to the supplier.

b) Payments for supply will be considered only after supply of **75%** of the quantity ordered is completed, PROVIDED reports of Standard Quality of the batch tested at a NABL accredited laboratory/ Central Drug Laboratory/ **South India Textile Research Association (SITRA), Coimbatore/ Defence Research and Development Establishment (DRDE) laboratories/ (as applicable)** is furnished along with the invoice. **In case of VTM, RNA Extraction Kits and RTPCR kits, In house COA is required to be furnished.** However, BMSICL shall be at liberty to get the quality of samples of each supplied batch verified/checked by RMRIMS, Patna before accepting the same. Where it is observed that for any batch of the supplies the report as above is not furnished, payment of the entire consignment would be withheld pending verifications and the entire consignment would be liable to be rejected.

c) All payments will be made only by way of electronic fund transfer NEFT transfer. The supplier shall desist from deputing their representatives to the head office of the Tender Inviting Authority for follow up for payments as the Corporation has a system of publishing the status of payments. *All communications in this regard shall be in writing and the Tender Inviting Authority discourages the visits, phone calls etc. as part of transparency policy.*

d) All *Bills/ Invoices* should be raised in **triplicate** and should be drawn as per the rules and regulations in force and provisions in this tender in the name of Managing Director, Bihar Medical Services and Infrastructure Corporation Limited, Patna. The original copy of invoice along with the test report to be submitted at the Regional Drug Warehouses/ scheduled delivery points along with the supply, duplicate and triplicate copies of invoice should be submitted in Headquarters along with the test report and other related documents. No payment will be affected if the above provisions are not complied with. Provision laid in **clause 20 (i) and (j)** shall be referred and read in consonance of this.

e) If at any time during the period of contract, the price of tendered items is reduced or brought down by any law or Act of the Central or State Government or by the bidder himself, or due to market forces below the contracted rate (for the assessment of

which a quarterly market survey shall be conducted item wise by the State Drug Control Department who will intimate the prevailing market rates to the BMSICL after every such survey), their contracted rate will stand reduced automatically to the reduced level. Failure to supply at the reduced rate shall be deemed as withdrawal from the tender and contract and shall be dealt with accordingly including counter offer to the next bidders i.e.- L-2, L-3 and so on respectively to match the reduced rates for further supplies. If supplies are made at higher rates after the rate of reduction, payments of the said supplies shall be made at the reduced rates only.

f) Fulfilling all the terms and conditions of the above said clause the payment will be released to the bidders within 30 days.

26. DEDUCTION OF PAYMENTS & PENALTIES

a) All supply should be made within the stipulated time and as per the summary of schedule and quantity as mentioned in the bid document/ PO.

b) If the supply reaches the Drug Warehouses beyond the stipulated time as mentioned in Bid document, liquidated damages will be levied at the rates mentioned therein for the delayed supplies.

c) Purchase orders will be cancelled under the conditions mentioned in Bid document after levying penalties at the rates mentioned therein and such penalty is recoverable from any amount payable to the supplier/ performance security.

d) However, the Tender Inviting Authority may receive supply even after expiry of the scheduled date from the date of purchase order, at its discretion, considering the urgency of the essential item for the user Institutions and in such case, liquidated damages will be levied at the rate mentioned in clause 21 supra.

e) If the supply is received in damaged condition it shall not be accepted. The supplier shall have to replace the goods with damage and the penalty equal to the penalty for unexecuted supplies will be levied for the damaged goods and payments will be withheld till proper replacement.

f) In all the above conditions, the decision of the Tender Inviting Authority shall be final and binding.

g) In case, the supplier has completed the supply of only 75% or more of the ordered quantity and has failed to supply 100% of the Ordered quantity within the scheduled supply period, then 20% of the value of non-supplied quantity against each purchase

order will be deducted/recovered from his performance security/any amount payable to supplier.

27. BLACK LISTING IN THE EVENT OF WITHDRAWAL FROM THE TENDER, AND NON-ADHERENCE TO THE QUALITY STANDARDS AND SUPPLY SCHEDULE

A: BLACKLISTING OF PRODUCT/TENDERER ON WITHDRAWAL OF TENDER

If the Tenderer fails to execute the agreement/ to deposit performance security/ to perform the obligations under the tender conditions/ commits default in the performance of the contract/ agreement, such Tenderers will be blacklisted for a period of **2 years** by BMSICL from the date of intimation besides forfeiture of EMD/ Performance Guarantee. The Tenderers who have withdrawn after participating in the tender either fully or partially, **the entire firm/ company** will be blacklisted for a period of **2 years** from the date of intimation by BMSICL apart from forfeiture of the Security Deposit/ EMD.

B. BLACKLISTING FOR QUALITY FAILURE IN QUALITY TEST BY THE EMPANELLED LABORATORIES OF BMSICL

1. Each and every batch of DRUGS, MEDICAL DEVICES/ CONSUMABLES supplied by the supplier shall be subjected to quality test by the Empanelled laboratories as per the procedure adopted by BMSICL.
2. If such Sample fails in *quality test for ASSAY* content of less than *50%* as per the Government Analyst report, such product of the supplier will be **de-registered/ debarred for one year (As Applicable)**.
3. If 3 batches of a particular item supplied by the supplier is reported to be failing in ASSAY content (above 50% but below prescribed limit) and/or other parameters, then the particular item of the firm shall be blacklisted for minimum of two years besides forfeiture of Security Deposit of that particular product(s).
4. If the supplier supplied more than one item and 50% of such items are blacklisted, the firm is liable to be blacklisted for a period of 2 years from the date of intimation.
5. If a single batch of any product(s) supplied by the company/ firm declared as Adulterated/ spurious/ Misbranded by the Government Authorities during the shelf

life of the product supplied irrespective of tender period, the company/ firm shall be blacklisted for a period of **2 years from the date of intimation & for feiture of security deposit.**

6. If a particular item of the Manufacturer/ Importer has been blacklisted the supplier is not eligible to participate in any of the tenders for that particular item floated by the BMSICL until the period of blacklisting is over.
7. If a supplier company/ firm is blacklisted, such supplier is not eligible to participate in any of the tenders floated by the BMSICL until the period of blacklisting is over.

C: BLACKLISTING FOR NON-SUPPLY/ PART SUPPLY/ DELAYED SUPPLY/ NON- FULFILLMENT OF CONTRACT OBLIGATION: -

Notwithstanding various actions and penalties for non-supply and/or delayed supply of the product as stipulated in the terms and conditions of the tender, the BMSICL, shall take action against the supplier as follows:

i. In case, the supplier is found to be habitual defaulter of delayed supply or not supplying the full quantity in time, the balance amount of performance security of such company shall be forfeited. No further supply order shall be given to them and company shall be barred from participating in any tender floated by BMSICL, further other punitive action such as blacklisting of the firm for a minimum period of 2 years from the date of intimation for blacklisting/ debarring.

ii. Purchase orders, if any, already issued before taking any blacklisting action or orders given in past will not be affected in view of action taken as per above guidelines but all strict quality checks shall be observed for each supply of products. The blacklisting of particular product or company/ firm will be done without prejudice to other penalties which may be imposed as per the conditions of Tender documents and also to other actions which may be initiated under Drugs and Cosmetics Act, 1940 or any other law of Land. BMSICL will display names of such blacklisted product(s) and company/ firm on its website for general notice.

28. SAVING CLAUSE

No suit, prosecution or any legal proceedings shall lie against Tender Inviting Authority or any person under him for anything that is done in good faith or intended to be done in pursuance of this tender.

29. APPLICABLE LAW & JURISDICTION OF COURTS

a) The contract shall be governed by and interpreted in accordance with the laws of India for the time being in force.

b) Any and all disputes arising out of this tender will be subject to the jurisdiction of courts of law/ tribunals situated in Patna, (Bihar) only or the Patna High Court only, as applicable.

30. RESOLUTION OF DISPUTES

a) Dispute or difference of any kind shall if arise between the Tender Inviting Authority and the successful bidder in connection with or relating to the contract, the parties shall make every effort to resolve the same amicably by mutual consultations. If the parties fail to resolve their dispute or difference by such mutual consultation within twenty-one days of its occurrence, then, unless otherwise provided in the Tender Document, either the Tender Inviting Authority or the successful bidder may give notice to the other party of its intention to commence arbitration, as per the provision applicable for arbitration procedure under the **Bihar Public Works Contracts Disputes Arbitration Tribunal Act 2008.**

b) In the case of a dispute or difference arising between the Tender Inviting Authority and a bidder relating to any matter arising out of or connected with the contract, such dispute or difference shall be referred to the sole arbitration of Principal Secretary, Health Department, Govt. of Bihar but if Managing Director/ Principal Secretary is same then Department of Health will decide the arbitrator.

c) Venue of Arbitration: The venue of arbitration shall be Patna (Bihar) India.

31. 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***.

32. GENERAL GUIDELINES FOR THE SUBMISSION OF E-TENDER

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

a) Registration of Tenderers: Any tenderer willing to take part in the process of e-Tendering will have to get himself enrolled & registered with the Government e-Procurement system, through logging on to https://eprocbihar.gov.in. The prospective Tenderer is to click on the link for e-Tendering site as given on the web portal.

b) Digital Signature Certificate (DSC): The bidder must have the Class II/III Digital Signature Certificate (DSC) and e-Tendering User-id of the e- Procurement websites before participating in the tendering process. The bidder may use their DSC if they already have the DSC. They can also take the DSC from any one of the authorized agencies. For user-id they have to get themselves registered on e-Procurement website www.eprocbihar.gov.in and submit their bids online on the same. Offline bids shall not be entertained by the Tender Inviting Authority for the Tenders published in e-Procurement platform.

c) 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.

d) Participation in more than one item: A prospective Tenderer is allowed to offer rate in more than one item as per his or her choice subject to fulfillment of conditions laid down hereinabove.

e) Submission of Tenders: General process of submission, Tenders are to be submitted online on the website at a time for each work, one in Technical Proposal & the other in Financial Proposal before the prescribed date & time using the Digital Signature Certificate (DSC) the documents virus scanned copy are to be uploaded duly Digitally Signed. The documents will get encrypted (transformed into non readable formats).

33. TERMINATION OF RATE CONTRACT: -

If at any point of time, the Tender Inviting Authority (TIA) becomes satisfied that:

a) There are sufficient evidence/ evidences of violation by the successful bidder of the conditions as laid down in this tender document, which subsequently form a part of the contract.
b) There are sufficient evidence(s) of wilful non-compliance of the conditions laid down in the contract by the supplier.
c) There are sufficient grounds for discontinuation of the contract.
d) A situation has come where there is no further requirement of materials stipulated for supply under the contract, he may order to terminate the entire contract or a part thereof and his order shall be binding on the parties concerned.

33 (A): -The bidders shall ensure compliance of conditions mentioned in the Annexure-X of this Bid document.

Note: **Please number the documents with serial number on each and every page and do mention the total number of pages of bidding document. In the technical Bid it is required to assign the corresponding page numbers of supporting documents. Any discrepancy or misrepresentation in this aspect will not be entertained.**

Sd/-
(Managing Director, BMSICL)
(Tender Inviting Authority)

Note-I- The Goods and Service Tax Registration Number of BMSICL is 10AAECB3969N1ZH.

Note-II- The bidders have to provide the detailed address of the Carrying and forwarding Agent/ Sales Depot point/ Dealership point/ Stockist point/ Distributor point in the State of Bihar including the Mobile Number so that Market survey can be done (if required). If your firm is not marketing the quoted products in State of Bihar and doesn't have any Carrying & Forwarding agent/ Sales Depot/ Dealership/ Stockist/ Distributorship then the bidder has to provide a self-declaration on the Firms letter head stating the same.

ANNEXURE- I

TENDERED PRODUCT LIST

Sl. No.	Name of the Products	Specification	Estimated Tendered Quantity
1.	PPE Kit with N-95 Mask	As per Annexure-XI	30,00,000 units
2.	N-95 Mask with Expiratory Valve	As per Annexure-XII	30,00,000 units
3.	3 Ply Face Mask	As per Annexure- XIII	5,00,00,000 units
4.	Face Shield with Head Cover	As per Annexure-XIV	20,00,000 units
5.	Reusable Vinyl gloves (For House Keeping)	Medium size: Covering Upto elbow region	1,00,000 pairs
6.	Disposable Nitrile Gloves **(Small)**	Nitrile □ Non-sterile □ Powder free □ Outer gloves preferably reach mid-forearm (minimum 280mm total length) □ Quality compliant with the following standards, or equivalent: a. EU standard directive 93/42/EEC Class I, EN 455 b. EU standard directive 89/686/EEC category III, EN 374 c. ANSI/SEA 105-2011 d. ASTM D6319-10	20,00,000 pairs
7.	Disposable Nitrile Gloves **(Medium)**		20,00,000 pairs
8.	Disposable Nitrile Gloves **(Large)**		10,00,000 pairs
9.	Hand Sanitizer 500 ml bottle	Each 100ml contains: Iso propyl Alcohol IP-75% v/v, Hydrogen Peroxide IP- 0.125%v/v, Glycerol IP- 1.45%v/v Solution. Or, Each 100ml contains: Ethanol IP-80%, Hydrogen Peroxide IP-0.125%v/v, Glycerol IP-	12,00,000 bottles

		1.45%v/v Solution.	
10.	Cetrimide Solution	2% w/v, 5 litre containers	1,00,000 containers
11.	Sodium Hypochlorite Solution	5%, 5 litre containers	2,20,000 containers
12.	Viral Transport Medium (With Double Swab)	As per Annexure-XV	25,00,000 test units
13.	Viral RNA Extraction Kit (Open System)	As per Annexure-XVI	15,00,000 test units
14.	RT- PCR KIT (Open System)	As per Annexure-XVII	1,00,000 test units

Note: - This is the centralized tender for the State of Bihar. The required quantity will be in accordance with the actual need as per the situation warrants.

ANNEXURE-II

AFFIDAVIT FOR NON-BLACKLISTING

I _____ Managing Director/Director / Partner / Proprietor of M/s._____having its manufacturing or import unit / registered office at_____ do hereby declare that thefirm & its quoted product have not been blacklisted currently (as on the date of submission of the tender) by Central Government/Central Government Agencies/any state government/any of the state government agencies/any Drug Procurement Agencies or by BMSICL. We are eligible to participate for the following quoted products:

S.N.	NIT S. N.	Name of DRUGS, MEDICAL DEVICES/ CONSUMABLES

Date: **Signature**

Seal:

(Authorised Signatory)
Name and Address of the Bidder

(Note: - This annexure must be sworn before First-Class Magistrate/Notary)

ANNEXURE-III

LIST OF ITEMS QUOTED

Tender No.: BMSIC/MEDICAL DEVICES / CONSUMABLES/20-01

Bidder Name:

S. N.	Name of the DRUGS, MEDICAL DEVICES/ CONSUMABLES	Specification	Pack size	Whether Manufacturer/ Importer	Mfg. / Import License No. and Date	HSN CODE	Date of issue of product approval by licensing authority	Mfg./ Import License and product approval valid up to
1								
2								
3								
4								
5								

Date: **Signature**

Seal:

(Authorised Signatory)
Name and Address of the Bidder

ANNEXURE-IV

AFFIDAVIT (Acceptance of tender conditions)

From: -

M/s.....

To

Managing Director,

BMSICL, Patna

1. I, _____Son/ Daughter/ Wife of Shri_____ Proprietor/Director authorized signatory of the agency/ Firm, mentioned above, is competent to sign this declaration and execute this tender document;

2. I have carefully read and understood all the terms and conditions of the tender and undertake to abide by them;

3. The information / documents furnished along with the above application are true and authentic to the best of my knowledge and belief. I / we, am / are well aware of the fact that furnishing of any false information / fabricated document would lead to rejection of my tender at any stage besides liabilities towards prosecution under appropriate law.

Yours faithfully,

Date: Signature

Seal:

(Authorised Signatory)
Name and Address of the Bidder

(Note: - This document must be sworn before First Class Magistrate/Notary)

ANNEXURE – V

Bidder Information/Bidder Details

Sl. No.	Name of the Particulars	The bidder shall fill required Information
1	Name of the Bidders (Manufacture / Importer) including registered address	
2	Name of Prime Manufacture (*ONLY FOR IMPORTERS*)	
3	Country of origin/registration: (*ONLY FOR IMPORTERS*)	
4	Legal status of the Bidder (Proprietorship/ Partnership/ Pvt. Ltd. Company/ Limited Company)	
5	Contact details of the bidder (Ph./ fax/ email)	
6	Name of Proprietor/ Managing Director/ Partners (as the case may be) with address	
7	Name and designation of authorized signatory	
8	Bank Details Name and address of Bank: Bank Account No.: IFSC Code of the Bank:	

Date:-

Place:-

(Authorised Signature)
Name of the authorised signatory
With full address

ANNEXURE VI

BIHAR MEDICAL SERVICES AND INFRASTRUCTURE CORPORATION LIMITED				
CHECK LIST FOR SUBMISSION OF TENDER				
S.N.	**Technical Eligibility Criteria as per NIT**	**Yes/No**	**Page No.**	**Remarks**
1	Documentary evidence of the constitution of the company/firm such as Memorandum and Articles of Association, Partnership Deed etc. should be submitted with details of the Name, Address, Telephone Number, Fax Number, E-mail address of the firm and of the Managing Director / Partners / Proprietor should be submitted as per Clause 3 (c)			
2	The details of Bidder Name, Address, Telephone Number, Fax Number, e-mail address of the bidder and of the Managing Director / Partners / Proprietor should be submitted in **Annexure-V**, as per Clause 3 (d)			
3	Power of Attorney or Resolution of the Board by which the authorized signatory has been authorized by the bidder firm to sign the documents should be submitted. As per clause 3(e).			
4	List of items quoted in prescribed format as per **Annexure-III** duly signed as per Clause 3 (m)			
5	Bidders must have: - (I) In case of manufacturer, the bidder firm must have a valid manufacturing license or duly acknowledged renewal application with old license issued by the State licensing authority/Central licensing approving authority under Drugs & Cosmetics (D&C) Rules 1945/ Medical Devices Rules 2017/ license issued by industry department or concerned government department, as applicable. • Approved product list as per the license issued for quoted MEDICAL DEVICES/CONSUMABLES as Drugs & Cosmetics (D&C) Rules 1945/ Medical Devices Rules 2017 where ever applicable. • Manufacturing License along with approved product list must be valid till the last date of the submission of tender (As Applicable). • Valid Pollution Control Clearance Certificate in			

	accordance with Water [Prevention and control of Pollution] Act, 1974 & Air [Prevention and control of Pollution] Act, 1981 and Hazardous Wastes (Management, Handling & Trans Boundary Movement) Rules 2008 (Self Attested Copy of Certificate to be enclosed) (as applicable). Bidders shall submit self-attested copies of required manufacturing license and approved product list in support of above-mentioned condition and they are required to specify the quoted products in their approved product list by highlighting it. (As Applicable) (II) In case of Importer, the bidder (importer) firm must have valid import license of the quoted product. All quoted products should be accompanied by their invoices, statement and import license showing that the quoted product is being imported and sold in India by the bidder (Importer firm). Import license must be valid on the last date of submission of tender. (III) In case of Non-drug item(s) where neither the Drugs & Cosmetics (D&C) Act 1945 nor the Medical Devices Rules 2017 is applicable the bidder must have a manufacturing license/import export certificate (IEC) with an undertaking/Self declaration as per **Annexure-VIII** that the item(s) quoted by the bidder is/are non-drug item(s) i.e. neither covered under D & C Act nor under Medical Devices Rules 2017.			
6	**Non-Conviction Certificate (NCC)** issued by the concerned Licensing Authority from Drugs Control Administration/ Concerned Government Department of the state should be submitted (As Applicable). It should be not more than one year old. Self-attested copies are			

	to be submitted. As per Clause 3(g).			
7	**WHO-GMP/GMP (**Good Manufacturing Practice) as per revised Schedule-'M'/COPP Certificate of the manufacturing unit issued by the Licensing Authority/ Drugs Control Department/BIS/ISI certificate issued from the concerned department (As Applicable). The GMP certificate should remain valid till the last date of submission of tender. Self-attested copies are to be submitted. **Explanation-** Generally the GMP Certificate issued for one-year validity. Hence the provision that it should not be older than one year from the last date of submission of tender implies mutatis mutandis that the GMP certificate should remain valid till the last date of submission of tender. As per Clause 3(h).			
8	**Maximum Batch Production Capacity Certificate** (section wise) issued by concerned Licensing Authority from Drugs Control Department/ Concerned Government Department high lighting the quoted product section (As Applicable). Self-attested copies are to be submitted. In case of Importer, an affidavit (with Stamp) sworn before first class magistrate/ Notary stating the batch production capacity of the firm and also that the **said production (Importing) capacity** shall be adequate for requirement laid in NIT. Importers will have also to submit Invoices/Evidence of import in items of said product with quantity details. The onus lies on the bidder to provide its production capacity through the production capacity (Self Declaration) to be submitted by the bidder as contained in Annexure-IX. This statement shall be in addition to the Production Capacity Certificate (section wise) obtained by the bidder from the concerned competent			

	authority. As per Clause 3(i).			
9	The tenderer should give an affidavit sworn before a First Class Magistrate/ Notary stating that the firm & its quoted product is not black listed currently (as on the date of submission of the tender) by Central Government/ Central Government agencies/any State Government or any of the State Government agencies/ or any Drug procurement agencies or by BMSICL as per **Annexure-II,** as per Clause 3(l).			
10	EMD details (DD number/BG number and date with issuing bank) as per Clause 3(b).			
11	Tender Fee Rs 10,000/- in form of DD as per Clause 3(a)			
12	Copies of the Audited Balance Sheet and Profit and Loss statement showing details of their annual average turnover not less than **5 Crores** for any three of the last four consecutive financial years (Auditor/CA certificate of turnover will not be accepted). Self-attested copies are to be submitted as per Clause 3(j)			
13	Copy of Income Tax Return for any three of last four consecutive Assessment years should be submitted (Self Attested copies). As per Clause 3(k).			
14	Copy of PAN Card of the bidder company should be submitted (self-attested). As per Clause 3(n).			
15	Copy of certificate of valid GST registration of the bidder company should be submitted (self-attested). As per Clause 3 (o)			
16	Affidavit declaration regarding acceptance of tender conditions to be submitted by the bidding firm as per Annexure IV (Clause 5(k) of NIT).			

Date: Signature

Seal:

(Authorised Signatory)
Name and Address of the Bidder

ANNEXURE VII

FORMAT OF BANK GUARANTEE OF EARNEST MONEY DEPOSIT

To,

The Bihar Medical Services and Infrastructure Corporation Limited
4th Floor, Bihar State Building Construction Corporation Limited
Hospital Road, Shastri Nagar, Patna-800023, Bihar

WHEREAS _____ (Name and address of the Company) (Hereinafter called "the bidder") has undertaken, in pursuance of tender no_____ dated _____ (herein after called "the tender") to participate in the tender of The Bihar Medical Services and Infrastructure Corporation Limited, (4th Floor, Bihar State Building Construction Corporation Limited, Hospital Road, Shastri Nagar,Patna-800023) with ……. (Description of goods and supplies)

AND WHEREAS it has been stipulated by you in the said tender that the bidder shall furnish you with a bank guarantee by a scheduled commercial bank recognised by you for the sum specified therein as Earnest Money Deposit for compliance with its obligations in accordance with the tender;

AND WHEREAS we have agreed to give the bidder ---------- (name and address) such a bank guarantee;

NOW THEREFORE we hereby affirm that we are guarantors and responsible to you, on behalf of the bidder, up to a total amount of _____ (Amount of the guarantee in words and figures), and we undertake to pay you, upon your first written demand declaring the bidder to be in default under the tender conditions and without cavil or argument, any sum or sums within the limits of (amount of guarantee) as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

We hereby waive the necessity of your demanding the said debt from the bidder before presenting us with the demand.

We undertake to pay you any money so demanded notwithstanding any dispute or disputes raised by the bidder(s) in any suit or proceeding pending before any Court or Tribunal relating thereto our liability under these presents being absolute and unequivocal.

We agree that no change or addition to or other modification of the terms of the tender to be performed there under or of any of the Tender Documents which may be made between you and the supplier shall in any way release us from any liability under this guarantee and we hereby waive notice of any such change, addition or modification.

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

This guarantee will not be discharged due to the change in the constitution of the Bank or the bidder(s).

The Conditions of this are as follows:-

1). If after bid opening the bidder withdraws his bid during the period of bid Validity specified in the form of bid;

OR

2). If the bidder having notified to the acceptance of his bid by the employer during the period of bid validity;

a) Fails or refuses to execute the form of agreement in accordance with the instruments to bidders, if required or

b) Fails or refuses to furnish the performance security, in accordance with the instruction to bidders.

We, _____ (indicate the name of bank) lastly undertake not to revoke this guarantee during its currency except with the previous consent, in writing, of The Bihar Medical Services and Infrastructure Corporation Limited.

This Guarantee will remain in force up to -------- (Date). Unless a claim or a demand in writing is made against the bank in terms of this guarantee on or before the expiry of ------(Date) all your rights in the said guarantee shall be forfeited and we shall be relieved and discharged from all the liability there under irrespective of whether the original guarantee is received by us or not.

(Signature with date of the authorised officer of the Bank)

…….

Name and designation of the officer

…….

…….

Seal, name & address of the Bank and address of the Branch

Bank Details of BMSICL:-

Account Holder Name:-Bihar Medical Services & Infrastructure Corporation Limited

Account No. :- 0140104000111072

IFS Code of Bank : - IBKL0000140

Bank Name : - IDBI Bank, Main Branch, Patna

Branch Name : - Uma Complex, Frazer Road, Patna-1

ANNEXURE VIII

AFFIDAVIT FOR NON-DRUG ITEM(S)

I _____ Managing Director/Director / Partner / Proprietor of M/s._____having its manufacturing or import unit / registered office at_____ do hereby declare that the quoted item is neither covered under Drugs & Cosmetics Act 1945nor Under Medical Device Rule 2017.We are eligible to participate for the following Non Drug item:

S.N.	NIT S. N	Name of Product

Date: Signature

Seal:

(Authorised Signatory)
Name and Address of the Bidder

(Note: - This annexure must be sworn before First Class Magistrate/Notary)

ANNEXURE IX

Production Capacity Statement (Self Declaration)

S. N.	PI. Mention Whether participating as a Manufacturer/ Importer	Mfg. / Import license number/ product registration certificate number	Validity of Mfg. / Import License.	Shelf life of the quoted item (s)	Standard Batch Size of the quoted item (s)	Monthly Production Capacity of the quoted item (s)	Annual Production Capacity of the quoted item (s)
1							

Authorized Signatory

Official Seal:

Date

ANNEXURE – X

World Bank Anti-Corruption and anti-fraud guidelines to be complied with, by the Bidders.

The bidders shall ensure compliance of conditions mentioned in the Annexure-X of this Bid document.

"*Fraud and Corruption: This Procurement is financed by the World Bank (the "Bank"). The Bank requires compliance with the Bank's Anti-Corruption Guidelines and its prevailing* sanctions policies and procedures as set forth in the WBG's Sanctions Framework, as set forth in following paragraphs. In further pursuance of this policy, bidders shall permit and shall cause their agents (whether declared or not), subcontractors, sub-consultants, service providers, suppliers and personnel, to permit the Bank to inspect all accounts, records and other documents relating to any initial selection process, prequalification process, bid submission, proposal submission and contract performance (in the case of award) and to have them audited by auditors appointed by the Bank.

1. **Purpose**

   The Bank's Anti-Corruption Guidelines and this annexure apply with respect to procurement under Bank Investment Project Financing operations.

2. **Requirements**

2.1 The Bank requires that Borrowers (including beneficiaries of Bank financing); bidders, (applicants/proposers), consultants, contractors and suppliers; any sub-contractors, Sub-consultants, service providers or suppliers: any agents (whether declared or not); and any of their personnel, observe the highest standard of ethics during the procurement process, selection and contract execution of Bank-financed contracts, and refrain from Fraud and Corruption.

2.2 To this end, the Bank:

a. Defines, for the purpose of this provision, the terms set forth below as follows:

   i. "corrupt practice" is the offering, giving, receiving, or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party:

   ii. "fraudulent practice" is any Act or omission, including misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain financial or other benefit or to avoid an obligation;

   iii. "Collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another part;

   iv. "Coercive practice" is impairing or harming or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party:

v. "obstructive practice" is:

a) Deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive, or collusive practice: and/or threatening, harassing, or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation: or

b) Acts intended to materially impede the exercise of the Bank's inspection and audit rights provided for under paragraph 2.2 c. below.

b. Rejects a proposal for award if the Bank determines that the firm or individual recommended for award, any of its personnel, or its agents, or its sub- consultants, sub-contractors, service providers, suppliers and/or their employees, has directly or indirectly, engaged in corrupt, fraudulent, collusive, coercive, constructive practices in competing for the contract in question:

c. In addition to the legal remedies set out in the relevant Legal Agreement may take other appropriate actions, including declaring misprocurement, if the Bank determines at any time that representatives of the Borrower or of a recipient of any part of the proceeds of the loan engaged in corrupt, fraudulent, collusive, coercive, or obstruction practices during the procurement process, selection and/or execution of the contract in question, without the Borrower having taken timely and appropriate action satisfactory to the Bank to address such practices when they occur, including by failing to inform the Bank in a timely manner at the time they knew of the practices:

Pursuant to the Bank's Anti-Corruption Guidelines and in accordance with the Bank's prevailing a nations policies and procedures, may sanction a firm or individual, either indefinitely or for a stated period of time, including by publicly declaring such firm or individual ineligible (i) to be awarded or otherwise benefit from a Bank-financed contact, financially or in any other manner (ii) to be a nominated sub-contractor, consultant, manufacturer or supplier, or service provider of an otherwise eligible firm being awarded a Bank-financed contract; and (iii) to receive the proceeds of any loan made by the Bank of otherwise to participate further in the preparation or implementation of any Bank-financed project.

ANNEXURE - XI

SPECIFICATION OF PERSONAL PROTECTIVE EQUIPMENTS (PPE) KIT WITH N-95 FACE MASK WITH EXPIRATORY VALVE

Various components of PPE KIT with N-95 Mask are as follows: -

i) **Coverall (garments)**
ii) **Goggles/ Face Shield**
iii) **Nitrile Gloves**
iv) **N-95 face mask with Expiratory Valve**

i) Specification of Coverall (Garments) with Tape over Seam along with Shoe cover: -

- The Fabric, Garment/Coverall and Seam should pass Synthetic Blood Penetration test at SITRA, Coimbatore/ DRDE Laboratories. Manufactures/suppliers submitting the pass certificate as above would be qualifying.
- Impermeable to blood and body fluids .
- Avoid culturally unacceptable colors e.g. black.
- Light colors are preferable to better detect possible contamination
- Coverall shall be designed to be universal Fit
- Coverall shall have in built Hood Cap
- Zipper of the coverall shall be covered with a flap to avoid accumulation of microbes
- Soft Elastic to be fitted around Front of hood, wrists & ankles
- Thumb/finger loops to anchor sleeves in place
- Quality compliant with following standard: - Meets or exceeds ISO 16603 class 3 exposure pressure, or equivalent.
- The PPE (Body Coverall for COVID-19) garment manufacturer will either print in indelible ink, or stick a tamper-proof sticker, on the body of the garment on the inside of the PPE with the following particulars;
    - Name of Manufacturer:
    - SITRA/ DRDO Unique Certification Code (UCC)
    - Test Standard
    - Date of Manufacturing/ Batch Number
    - BIHAR GOVERNMENT SUPPLY – NOT FOR SALE
    - BMSICL Logogram
- Boot Cover: Pair of Boot Covers made of same fabric as of Coverall

  Soft elastic to be fitted at two levels, ankle and end.

NOTE:

1) Bidders shall quote for the complete knitted coverall (for head to toe)

2) Garments must be tested for Synthetic Blood Penetration Resistance Test conducted at SITRA, Coimbatore/ DRDE Laboratories for fabric, Garment, complete knitted suit and feet/Shoe cover. The test report must be submitted along with this bid.

3) The interested bidders must have to comply with the Quality Control Mechanism in accordance with the rules and regulations of Ministry of Textiles, Government of India.

ii) Specification of Goggles/ Face Shield: -

a) Specification of Goggles:

- With transparent glasses, zero power, well fitting, covered from all sides with elastic band/or adjustable holder.
- Good seal with the skin of the face.

- Flexible frame to easily fit all face contours without too much pressure.
- Covers the eyes and surrounding areas and accommodates for prescription glasses.
- Fog and scratch resistant.
- Adjustable band to secure firmly so as not to become loose during clinical activity.
- Indirect venting to reduce fogging.
- May be re-usable (provided appropriate arrangements for decontamination are in place) or disposable.
- Quality compliant with the below standards, or equivalent:
- EU standard directive 86/686/EEC, EN 166/2002
- ANSI/SEA Z87.1-2010

b) Specification of Face Shield

- Made of clear plastic and provides good visibility to both the wearer and the patient.
- Adjustable band to attach firmly around the head and fit snuggly against the forehead.
- Fog resistant (preferable).
- Completely covers the sides and length of the face.
- May be re-usable (made of material which can be cleaned and disinfected) or disposable
- Quality compliant with the below standards, or equivalent:
  a. EU standard directive 86/686/EEC, EN 166/2002
  b. ANSI/SEA Z87.1-2010

iii) Specification of Nitrile gloves (Size 6.5, 7 & 7.5): -

- Nitrile
- Non-sterile
- Powder free
- Outer gloves preferably reach mid-forearm (minimum 280mm total length)
- Different sizes (6.5, 7 & 7.5)
- Quality compliant with the below standards, or equivalent:
  a) EU standard directive 93/42/EEC Class I, EN 455
  b) EU standard directive 89/686/EEC category III, EN 374
  c) ANSI/SEA 105-2011
  d) ASTM D6319-10

iv) Specification of N-95 Masks with Expiratory Valve: -

- Shape that will not collapse easily.
- High filtration efficiency.
- Good breathability, with expiratory valve.
- Quality compliant with standards for surgical N95 respirator:
  NIOSH N95, EN 149 FFP2, or equivalent.
- Fluid resistance: minimum 80 mm Hg pressure based on ASTM F1862, ISO 22609, or equivalent.
- Quality Compliant with standards for particulate respirator that can be worn with full-face Shield.

All batches to be supplied need to be accompanied with certificate of analysis from national/international organizations/labs indicating conformity to standards.

ANNEXURE - XII

SPECIFICATION OF N-95 FACE MASK WITH EXPIRATORY VALVE

- Shape that will not collapse easily.
- High filtration efficiency.
- Good breathability, with expiratory valve.
- Quality compliant with standards for surgical N95 respirator:
  NIOSH N95, EN 149 FFP2, or equivalent.
- Fluid resistance: minimum 80 mm Hg pressure based on ASTM F1862, ISO 22609, or equivalent.
- Quality Compliant with standards for particulate respirator that can be worn with full-face Shield.

All batches to be supplied need to be accompanied with certificate of analysis from national/international organizations/labs indicating conformity to standards.

ANNEXURE - XIII

SPECIFICATION OF 3 PLY FACE MASK

1. Fabric: - Melt Blown, Non-Woven fabric.
2. Construction: - 3-ply type construction.
3. Colour: - Blue.
4. Sealing: - No loose sealing.
5. Size: -not less than 17cm x 09cm.
6. Tying straps: - 4 nos.
7. Filtration efficiency: - not less than 99% for 3-micron particle size.
8. Nose Clip: - Plastic coated rust proof nose clip.
9. Packaging: - 100 nos. in each poly bag with adequate labelling/ noting.
10. Each poly bag must be labeled with the above said specification along with BMSICL Logo and BIHAR GOVT. SUPPLY NOT FOR SALE.
11. **Must have ISO- 22609:2004 and CE/ GMP certification.**
12. **The bidder has to submit the test report of any earlier batch of the product from any NABL Accredited Laboratory along with the technical bid document.**

All batches to be supplied need to be accompanied with certificate of analysis from national/international organizations/labs indicating conformity to standards.

ANNEXURE – XIV

SPECIFICATION OF FACE SHIELD WITH HEAD COVER

A) SPECIFICATION OF FACE SHIELD

- Made of clear plastic and provides good visibility to both the wearer and the patient.
- Adjustable band to attach firmly around the head and fit snuggly against the forehead.
- Fog resistant (preferable).
- Completely covers the sides and length of the face.
- May be re-usable (made of material which can be cleaned and disinfected) or disposable
- Quality compliant with the below standards, or equivalent:
  a. EU standard directive 86/686/EEC, EN 166/2002
  b. ANSI/SEA Z87.1-2010

B) SPECIFICATION OF HEAD COVER

Surgical Head cover, disposable type, should be manufactured from non-woven fabric Blue/ Green/ colour Round upon wearing, with elastic Air permeable/ breathable, should retain skin and hair particles.

All batches to be supplied need to be accompanied with certificate of analysis from national/international organizations/labs indicating conformity to standards.

As and when required the Face Shield and Head Cover shall be used separately.

ANNEXURE – XV

SPECIFICATION OF VIRAL TRANSPORT MEDIUM WITH DOUBLE SWAB TYPE (ICMR APPROVED)

1. **The VTM Kit (Double Swab) should be ICMR Approved.**
2. Required for transport of swab samples for testing of Viral Infections like; SARS-CoV-2, H1N1 etc.
3. Composition of the medium should be as per specified by WHO/CDC/ NCDC.
4. 10-15 ml volume screw- cap, leak- proof plastic tube.
5. Should contains 3 ml viral transport media.
6. The media should be clear and pink in Colour.
7. The medium should be stable at room temperature
8. pH 7.3 (+/- 0.3)
9. Osmolality in mOsm/Kg H2O 500.00-600.00
10. It should contain a protective protein antibiotic to control microbial contamination and buffers to control the pH.
11. Shelf life should be at least one year at the time of delivery.
12. Method of sterilization and date of expiry should be mentioned both on the box and individual tubes.
13. Each tube should have a label for writing patient details.

SPECIFICATION OF STERILE DACRON/ POLYESTER/RAYON SWAB WITH BREAKPOINT

1. Two sterile synthetic fibre swabs (Dacron/ Polyester/ Rayon) with plastic shafts or wire shaft (flexible shaft).
2. Swabs should be appropriate for collection of nasopharyngeal and oropharyngeal samples for viral testing.
3. It should be flexible an provided with breakpoint.
4. The swabs should be packed individually.
5. Method of sterilization and expiry should be mentioned on the wrapper.
6. **No quote for "Single Swab VTM" supplemented with additional (Separate) swab will be entertained.**

ANNEXURE – XVI

SPECIFICATION OF VIRAL RNA EXTRACTION KIT (ICMR APPROVED)

1. **The Viral RNA Extraction Kit should be ICMR Approved.**
2. Kit should work with silica membrane column / magnetic bead-based technology allowing extraction of Viral RNA From Human Samples (Plasma, CSF, Urine, Other cell-free body fluids and Cell-culture supernatants.
3. The Viral RNA extracted using this kit should be used for downstream applications like PCR, qPCR, real-time PCR.
4. Kit should extract Viral RNA using sample volume between 100µl - 200µl and Elution volume between 40 µl - 80 µl.
5. The process of extraction using the kit should be either centrifugation/vacuum based/magnetic bead based.
6. Carrier RNA should be used in the kit to capture maximum amount of the Viral RNA from sample and carrier RNA Should help viral RNA to escape from degradation by RNases.
7. Time per extraction should be 30-60Min.
8. Yield of the Viral RNA should be >90% recovery.
9. The Elution buffer should have necessary components to prevent microbial growth and contamination with RNAs.
10. Should be optimized for use with biological fluids and cell-free samples such as serum, plasma, swabs, and cell culture medium.

ANNEXURE – XVII

SPECIFICATION OF COVID- 19 RT-PCR TEST KIT (ICMR APPROVED)

1) Suitable for in-vitro qualitative detection of SARS-CoV-2 nucleic acids in throat (oropharyngeal) swabs, nasopharyngeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates and Broncho alveolar lavage fluid (BALF) from individual who are suspected of COVID-19.

2) The RTPCR COVID-19 test kit should have necessary certification/ approval as per the prevailing ICMR guidelines. (Necessary certificates or approval copy of quoted kit must be furnished in the technical bid)

3) The COVID-19 RTPCR Test kit should be validated and approved by any of the ICMR Validation centres. The bidder must enclose the satisfactory validation report issued from any of the approved ICMR Validation centres.

4) The Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 should use fluorescent probe based TaqMan chemistry with multiplex reaction. Probes should have reporter dyes in the range of yellow and Green channels, to have compatibility with all types of real time PCR platform (machines).

5) If the kit is representing only one gene it should be of SARS CoV-2 specific only and should have an internal control of human housekeeping gene.

6) Multiplex detection (combination of screening and confirmatory assays) should have screening E gene along with confirmatory genes of ORF/RdRP/N genes of SARS-CoV-2 along with human housekeeping gene/ any internal control gene to assess sample quality, RNA extraction and RT PCR reaction.

7) The assay should be robust and compatible with RNA extracted using different viral RNA extraction kits available in the market.

8) The kit supplied should be open ended, compatible to any kind of RT-PCR machine available in market.

9) Product should be CE as per IVD (Invitro Diagnostic Device)/ USFDA/ ICMR Certified.

-END-