

## eProcurement System Government of Uttar Pradesh

## Tender Details

Date : 06-May-2022 12:02 PM

Print

## Basic Details

Organisation Chain	Sanjay Gandhi Post Graduate Institute of Medical Sciences Lucknow  Materials Management Department		
Tender Reference Number	I/06/JDMM/2022-23		
Tender ID	2022_SGPGI_696661_1		
Tender Type	Open Tender	Form of contract	Item Wise
Tender Category	Goods	No. of Covers	2
General Technical Evaluation Allowed	No	ItemWise Technical Evaluation Allowed	No
Payment Mode	Offline	Is Multi Currency Allowed For BOQ	No
Is Multi Currency Allowed For Fee	No	Allow Two Stage Bidding	No

## Payment Instruments

Offline	S.No	Instrument Type
	1	RTGS - RTGS Payment

## Cover Details, No. Of Covers - 2

Cover No	Cover	Document Type	Description
1	Fee/PreQual/Technical	.pdf	TECHNICAL BIDS
2	Finance	.xls	FINANCIAL BIDS

## Tender Fee Details, [Total Fee in ₹ \* - 29,500]

Tender Fee in ₹	29,500		
Fee Payable To	DIRECTOR SGPGI	Fee Payable At	Lucknow
Tender Fee Exemption Allowed	No		

## EMD Fee Details

EMD Amount in ₹	36,00,500	EMD through BG/ST or EMD Exemption Allowed	Yes
EMD Fee Type	fixed	EMD Percentage	NA
EMD Payable To	DIRECTOR SGPGI	EMD Payable At	Lucknow

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## Work / Item(s)

Title	EXECUTION OF RATE CONTRACT OF ANTI HEMOPHILIC FACTORS				
Work Description	EXECUTION OF RATE CONTRACT OF ANTI HEMOPHILIC FACTORS				
Pre Qualification Details	Please refer Tender documents.				
Independent External Monitor/Remarks	NA				
Show Tender Value in Public Domain	Yes				
Tender Value in ₹	36,00,00,000	Product Category	Medicines	Sub category	NA
Contract Type	Rate Contract	Bid Validity(Days)	180	Period Of Work(Days)	60
Location	ITEMS	Pincode	226014	Pre Bid Meeting Place	NA
Pre Bid Meeting Address	NA	Pre Bid Meeting Date	NA	Bid Opening Place	JDMM OFFICE
	No		No		

Should Allow NDA Tender	Allow Preferential Bidder
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Critical Dates			
Publish Date	06-May-2022 12:15 PM	Bid Opening Date	06-Jun-2022 11:00 AM
Document Download / Sale Start Date	06-May-2022 12:15 PM	Document Download / Sale End Date	04-Jun-2022 05:00 PM
Clarification Start Date	06-May-2022 12:15 PM	Clarification End Date	10-May-2022 11:00 AM
Bid Submission Start Date	10-May-2022 11:00 AM	Bid Submission End Date	04-Jun-2022 05:00 PM

### Tender Documents

NIT Document	S.No	Document Name	Description	Document Size (in KB)	
	1	Tendernotice_1.pdf	TENDER DOCUMENTS OF ANTI HEMOPHILIC FACTORS	20607.96	
Work Item Documents	S.No	Document Type	Document Name	Description	Document Size (in KB)
	1	Additional Documents	BOQAHF.pdf	BOQ	585.77

### Bid Openers List

S.No	Bid Opener Login Id	Bid Opener Name	Certificate Name
1.	hrf@sgpgi.ac.in	R A Yadav	R A YADAV
2.	rktiwari@sgpgi.ac.in	Rajesh Tiwari	RAJESH KUMAR TIWARI
3.	sb.sb55@gmail.com	Suresh Bahadur Singh	SURESH BAHADUR SINGH
4.	shiv_math2002@yahoo.com	MANOJ KUMAR SRIVASTAVA	MANOJ KUMAR SRIVASTAVA

### Tender Properties

Auto Tendering Process allowed	No	Show Technical bid status	Yes
Show Finance bid status	Yes	Show Bids Details	Yes
BoQ Comparative Chart model	NIL	BoQ Compative chart decimal places	2
BoQ Comparative Chart Rank Type	NIL	Form Based BoQ	No

### Tender Inviting Authority

Name	DIRECTOR SGPGI
Address	ADMIN BLOCK, SGPGIMS, LUCKNOW

### Tender Creator Details

Created By	MANOJ KUMAR SRIVASTAVA
Designation	AAO
Created Date	06-May-2022 11:42 AM



Hindustan, Lucknow

Date: 03.05.2022



**SANJAY GANDHI POST GRADUATE  
INSTITUTE OF MEDICAL SCIENCES**  
RAEBARELI ROAD, LUCKNOW-226014  
Telo: 0522-2494038 e-mail: jdmms@sgpgi.ac.in  
**MATERIALS MANAGEMENT DEPARTMENT**

**e-Tender Notice**

**Tender No.: PGI/MM/AHF/2022-23/01**

Online offers are invited in Two bid system (1) Technical Bid in two Parts (1-A) Checklist (Essential Documents) (1-B) Technical details of required products including catalogue, etc. (2) Price Bid as per BOQ, from reputed & genuine manufacturers/ their authorized Importers only, for executing a rate contract for Anti-Hemophilic Factors for a period of two (02) years.

The bidders are required to submit their online offers w.e.f. 06.05.2022 (1100 hrs) on e-tender portal only i.e. [www.etender.up.nic.in](http://www.etender.up.nic.in) in two bids system as mentioned above. For detailed information like Name of item, Specifications, Terms & Conditions, Last date of Submission of online offer against tender, Earnest Money Deposit, Opening of Technical Bids, etc, you may please visit the e-tender portal [www.etender.up.nic.in](http://www.etender.up.nic.in). The above details will also be available on our website i.e. [www.sgpgims.org.in](http://www.sgpgims.org.in) for reference only. The offers will be accepted On-line only on e-tender portal with terms and conditions as mentioned in tender documents. No offers shall be accepted off-line.


The Director reserves the right to accept or reject any offer partially or fully without assigning any reason.

ADVT No. 106/JDMM/2022-23

**DIRECTOR**

### Salient points of the Notice Inviting Tender

- Online offers are invited in Two bid system **(1) Technical Bid** in two Parts (1-A) Checklist (Essential Documents) (1-B) Technical details of required products including catalogue etc. **(2) Price Bid as per BOQ**
- Bids will be accepted from reputed & genuine manufacturers / importers only.
- Cost of tender document (Non-refundable) : Rs. 29,500.00 (Rs. 25,000.00 for tender fee + Rs. 4,500.00 for GST)
- Earnest Money Deposited (Refundable) : Rs. 36,00,500.00 (Thirty Six Lakh Five Hundred Only)
- Performance Security : Performance Security @ 5% of estimated value for 01 year of approved item (s) but maximum to the limit of Rs. 1,00,00,000.00 (Rs. One Crore Only) shall be submitted by the successful bidders within 15 days from the date of award of rate contract in shape of Bank Guarantee in favour of "Director, SGPGIMS, Lucknow". The Bank Guarantee shall be valid till period of rate contract. The EMD amount of Rs. 36,00,500.00 (Thirty Six Lakh Five Hundred Only) of eligible bidders for award of rate contract will be returned once the Bank Guarantee is deposited by the firm/Rate Contract holder. The EMD of unsuccessful bidder shall be returned after finalization of rate contract/tender.
- Submission of bid/Offer : The bids should be submitted On-line as specified.
- Validity of offer : 365 Days/till validity of rate contract.
- The rate contract may be awarded to : The successful bidder for a period of 02 (two) years on yearly renewal basis subject to satisfactorily performance of previous years. The rate contract may be extended for a period of 3 months after the expiry of 02 years or till the finalization of new rate contract whichever is earlier, if required.
- The terms & conditions of the NIT : will be submitted duly signed and stamped by the bidder along with technical bid.

  
 Rajesh Kashyap  
 State Nodal Officer  
 Hemophilia Program &  
 Blood, Dept. of Hematology  
 SGPGIMS, Lucknow-226014



- Use separate sheet in the same format in case of need of more space.
- The award of rate contract is not linked with procurement style opted by institute during the entire period of rate contract. Any item under rate contract may be procured through supply order. Modality of procurement and inventory management of any item may be changed at any point of time.

### **General Terms & Conditions of above NIT**

1. List of tendered item i.e. scope of supply is attached at – **Annexure-IX**
2. Some of the items may be kept on utilization or consignment basis as elaborated in the tendered list as per Annexure-IX.
3. The firms, who are intended to participate in the tender, should first ensure that they fulfill all eligibility criteria as prescribed:
  - i. Bidder having a average annual turnover of Rs. 5.00 crores (Rupees Five Crores) during the last three years i.e., 2019-20, 2020-21 and 2021-22 will be eligible for participation in this Rate Contract. Firms will have to submit audited financial statement for the above three years in support of annual turnover. In case where Audited balance sheets of 2021-22 is not available , the bidder shall submit audited balance sheets of three years ( 2018-19, 2019-20 and 2020-21) along with provisional balance sheet of 2021-22. In such a case the average annual turnover of bidder for the three years (2018-19, 2019-20 and 2020-21) should also be Rs. 5.00 crores or more and Turnover for the year 2021-22 should also be Rs. 5.00 crores or more.  
Turnover should be in respect of firm/bidder submitting the tender. Group turnover will not be considered for determining the eligibility and such tenders will be rejected summarily.
  - ii. The bidder /manufacturer must have WHO-GMP certificate i.e., Good Manufacturing Practices (GMP) Certificate in accordance with the W.H.O and must possess the item-wise COPP (Certificate of Pharmaceutical Product) as per WHO technical report series scheme for the drugs quoted.  
If it is found subsequently that the WHO-GMP certificate has been issued not in accordance with the guidelines issued in this regard by the Drug Controller General of India (which includes joint inspection of the manufacturing unit by central and state drug control authorities), the certificate as well as the tender are liable to be rejected. The WHO-GMP certificate should be submitted.  
The firm should also submit the self-attested copies of USFDA/Research molecule certificate (in case of Research molecule), manufacturing certificate or provide evidence of supply the tendered product to countries including in the 'very high human development' list of countries of the world for internal use in those markets if applicable. These will be included as factor to judge quality.
  - iii. For proprietary drugs, the bidder has to submit the proprietary certificate of the

manufacturer (Principal firm).

- iv. For the drugs which are being imported, the firm should possess valid import license issued by the Drug Controller General of India and DGS&D and marketing license issued by concerned Licensing Authority.
- v. Firm should have a valid drug manufacturing license from the State Drug Controller for the drug / drugs quoted and must submit a attested copy of the same.
- vi. For the drugs quoted in the tender enquiry, firm will have to submit the samples on demand. If firm fails to submit the samples, the tender will be rejected outrightly.
- vii. Firm should submit Non Conviction Certificate (N.C.C.) issued by the State Drug Controller, to the effect that the manufacturer has not been convicted under the Drugs and Cosmetics Act, 1940 and rules there under during the preceding three years for any of the drugs for which he has quoted price and that no case / proceedings is pending against the manufacturer in any Court of Law in India under the Drugs & Cosmetics Act. The Non-Conviction Certificate (N.C.C.) should be in respect of drug licence from which the firm has quoted. The N.C.C. should be latest and should not be more than 01 (one) year old.
- viii. The bidder should not have been debarred /blacklisted / de-registered by any Government Undertaking in India. The bidder should submit a notarized undertaking/affidavit certifying that the bidder is not debarred/blacklisted or de-registered by any Government or Government undertaking in India. The bidder should also not have been debarred /blacklisted /de-registered by any Government Department /Government Undertaking/ Government Procurement agency for the any of the item quoted by the bidder or convicted by any court of law.
- ix. Past performance of the bidder will be taken into consideration for evaluation of bids / award of Rate Contract. Bids of the bidders whose samples have failed frequently in the past or who have frequently made defaults in execution of orders issued under the Rate Contract (Delay in supply/non execution of orders etc. in the manner specified in Rate Contract and supply order) shall be liable for rejection.

If the firm has so many divisions in that condition the tender should be submitted by each division separately.

4. The tenderer submitting his/her tender would be deemed to have thoroughly read, considered and accepted all the terms & conditions. No enquiries shall be entertained in respect of acceptance or rejection.
5. Tenderer should clearly state whether he/they are manufacturer/importer.
6. Tenderer shall submit the pre-requisite information as per format attached.



7. Tenderer would be responsible for any error. If, the submitted tender have any kind of error, the tender will liable to be rejected.
8. The rate contract will be governed by the conditions laid down in the tender documents.
9. A rational balance of quality, quantity & cost of product offered / quoted by the firms meeting the eligibility criteria shall be the sole basis of awarding the contract.
10. Online offers are invited in Two bid system **(1) Technical Bid** in two Parts (1-A) Checklist (Essential Documents) (1-B) Technical details of required products including catalogue etc. **(2) Price Bid as per BOQ**, from reputed & genuine manufacturers/ importers only, for executing a rate contract for a period of 02 (two) years on yearly renewal basis subject to satisfactorily performance of previous years. The rate contract may be extended for a period of 3 months after the expiry of 02 years or till the finalization of new rate contract whichever is earlier, if required.

**(1-A) Checklist with all the related essential documents such as:-**

- i. Tender document downloaded from specified website
- ii. The tenderer shall submit their bids online as specified in <https://etender.up.nic.in>. The off-line tender will not be considered under any circumstances. The tender fee of Rs. 29,500.00 (Rs. 25,000 for tender fee + Rs. 4,500 for GST) and Earnest Money Deposit (EMD) of Rs. 36,00,500.00 (Thirty Six Lakh Five Hundred Only) will also be submitted online separately as per following details and receipt / proof of the same must be attached with the checklist of technical bid:
  - (a) Account Number- 10095237355
  - (b) Name of Account – Director, SGPGI
  - (c) Name of Bank and Branch – State Bank of India, SGPGIMS Branch, Lucknow - 226014
  - (d) IFSC Code- SBIN0007789

For online refund of EMD, following details be provided by the bidders in technical bid:

- (a) Tender number
- (b) Name of drugs, quoted for
- (c) Amount of EMD
- (d) Name of Bank and Branch
- (e) IFSC Code
- (f) Name of account
- (g) Account number in which EMD amount is to be credited
- (h) UTR Number
- iii. Documents as per **Annexure – ( VI,VII and VIII)**
- iv. Details of Income Tax/PAN
- v. Self attested copies of GST return.
- vi. Non-conviction /No pending conviction certificate affidavit & never been blacklisted/debarred issued by Notary for preceding three years.
- vii. Self-Attested copies of manufacturing / import license for each and every product as the case may be.
- viii. Self-Declaration on Rs 10/-Non-Judicial stamp paper duly notarized about lowest rate & downward rate revision (**Annexure-IV**)
- ix. Three years manufacturing / marketing certificate from competent authority. In case of importer, evidence for processing import license & actually importing similar generic items (Factor VIII, IX & Factor VIII with vWF) for last three (03) years. In case any of the



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above mentioned drugs fall under 'New Drug' category according to The Gazette of India and Import License issued by Directorate General of Health Services (DGHS) Central Drugs Standard Control Organization, Govt. of India, the submission of 03 years Import Proof/Bill of Entry and manufacturing & marketing certificate shall not be applicable. **(Annexure-I)**

- x. Documentary evidence stating the status of the bidder i.e. Proprietorship/Company etc.
- xi. List of procurement agencies of repute to which the tendered products have been supplied during last 12 months with performance certificate.
- xii. Self attested copies of annual report, audited balance sheet and profit and loss account for preceding three years for support of claims regarding turnover etc.
- xiii. An affidavit (Notarized) that tenderer does not have any relation with the person authorized to evaluate technically or involved in finalizing the tendered items **(Annexure-V)**
- xiv. Notarized affidavit for the effect that the firm is not debarred/blacklisted/punished by Drug Controller of India/State Drug Controller.
- xv. The certificate of Drug license.

**(1-B) Technical Bid consisting of following :**

- I. Product catalogue for the items quoted in the tender in original. All the related documents which are needed for the items quoted in the tender.
- II. All forms related to the tender duly filled in stamped and signed by the bidder.

**(1-B) Technical Bid consisting of following :**

- I. Product catalogue for the items quoted in the tender in original. All the related documents which are needed for the items quoted in the tender.
- II. All forms related to the tender duly filled in stamped and signed by the bidder.

**2. Price Bid:** - The Price Bid should be super-scribed as "Price Bid against tender No... for hemophilic factor and should contain the following documents in the price bid:

- o Price bid in prescribed in e-tender portal / Materials Management form duly filled in, stamped and signed by the tenderer, neatly typed and price should be in words and figures both (Annexure-III).
- o All quoted rates should be for one unit (IU/Unit/mg). Rate should be mentioned in word & figure both. If, the rates does not match in word & figure, the rates mentioned in word will only be considered.
- o Tenderer must ensure that the quoted rates are inclusive of GST or any Govt. levies as applicable. Institute will only accept the material, which would be GST paid, if applicable and should be inclusive of all taxes / levies including CGST & SGST as applicable.
- o All quoted rates should be F.O.R. destination as, will be mentioned in supply order at different medical centres in UP.
- o Quoted item list serial no. should be the same serial no. as detailed in item list of tender document.
- o Tenderer should quote firm and fixed rates.
- o Free goods will be incorporated in price comparison.



- The specification and size of each product should be as per details given in tender.
  - Any variation may result in the rejection of the tender.
  - Please of clerical error, typographical error etc. committed by the tenderer would not be accepted and tender will liable to be rejected.
  - No correspondence will be entertained after opening of the price bid.
  - The prices quoted by the tenderer shall not in any case exceed the controlled price, if any, fixed by Central/State Government and Maximum Retail Price(MRP)
  - **Institutional price list of company must be attached duly signed and stamped by the principal firm in separate sheet.**
  - Any conditional price bid would not be entertained and the submitted tender will liable to be rejected.
3. The tenderer should submit the tender document online in original, supporting copies / document should be self attested.
  4. No tender will be accepted unless the full amount of the tender fee including GST & EMD are paid online as per details mentioned in tender document and transaction reference / proof of payment are attached with technical bid.
  5. Validity of offer should mention as per tender requirement i.e. till validity of R/c.
  6. The tenderer must submit copy of their drug-manufacturing license and / or Import license and its validity period for the items quoted. If the license is under renewal, it should be confirmed that application for renewal was made within the period as per Drugs & Cosmetics Act, 1940 as amended up to date and the Licensing Authority has not deleted the item as on date.
  7. The tenderer should also indicate the life of goods expiry offered by them. They should also note that the stores offered for inspection against the contract, if any, placed by the purchaser shall not have passed more than 1/4th of their useful life from the date of manufacture. Loss or premature deterioration due to biological and or other factors during life span of stores shall have to be made good by the contractor free of cost.
  8. The tenderer is also informed that the stores offered by him should strictly confirm to the provisions of the Drugs & Cosmetics Act, 1940 and the Rules made there under as amended from time to time. Consignment should be properly and securely packed as per general condition of the contract. Consignment should be marked with the purchaser's supply order No. and date & must be stamped as 'Hospital Supply' on each vials before delivery.
  9. The Institute reserves the right to negotiate with qualifying firms.
  10. Stores supplied to any authority other than SGPGI will not be taken into cognizance and no bills / payment claims what so ever would be accepted against such supplies.
  11. Tenderer should uphold the good business practices.
  12. Release of EMD
    - (i) The Institute will return EMD of successful bidders once performance security is deposited by the firm.
    - (ii) The bidders who has/have not awarded Rate Contract can take their EMD immediately after finalization of Rate Contract after due correspondence.
  13. Each & every page or paper of the tender document should be serially numbered, signed & stamped by an authorized signatory of the bidder.

14. All bids should clearly specify the bidders name & full postal address, telephone no. mail id etc.
15. If the dates mentioned above are declared Government holiday then the date shall automatically be shifted to next working day.
16. The tender documents / bids will be received On-line only. Offline offers will not be considered.
17. Disqualification of the tender:
  - o Any action on the part of tenderer to influence any official of the Institute will amount to rejection of his bid.
  - o Lack of any formalities in Tender Documents (as per Check List).

**Procurement on supply order basis:**

Supply of material covered under this rate contract will be made on the basis of written supply order with terms and conditions enumerated therein. It will be the responsibility of supplier to have an access with Institute/State Nodal Officer, Hemophilia to maintain the optimum inventory level. This has been decided to tide over the problem of over stocking including near expiry/ slow moving/ non-moving inventories, for which following mechanism will be observed:

- i. Besides having liasoning with Institute/State Nodal Officer will be allowed to have access to computerized system to know the consumption pattern / reports of the items concerned.
- ii. In hand stock position at Institute stores and peripheral sub stores can also be obtained from time to time.
- iii. Access to SGPGI stores to know the status of expiry / slow moving / non-moving products.
- iv. Company will own the responsibility of over stocking & expiry.
- v. Company will actively take preventive measures and inform SNO/JD (MM) in writing about any specific item/quantity mentioned in supply order that may lead to overstocking /expiry.
- vi. In case of any difficulty in getting the feedback, you may contact State Nodal Officer, Hemophilia (SNO) / Joint Director (MM) (SGPGI) /Director.

You will agree that any loss of material is going to be a national loss. Please do inform about such items asked for supply but may not be required by the users. In case of any difficulty in getting the feedback, you may contact State Nodal Officer, Hemophilia (SNO) / Joint Director (MM) (SGPGI) /Director.

11. **Period of validity:** The Rate Contract will be valid for a period of 02 (two) years on yearly renewal basis subject to satisfactorily performance of previous years. The rate contract may be extended for a period of 3 months after the expiry of 02 years or till the finalization of new rate contract whichever is earlier, if required.



**12. Authority to the purchase:**

Any officer designated by the Institute shall be entitled to exercise all the rights and powers given in the contract.

**13. Responsibility of the Tenderer for executing the contract:**

The tenderer shall perform the contract in all respect in accordance with the terms and conditions mentioned therein. The tenderer shall remain responsible until the actual delivery of the goods is made to the consignee at the stipulated place.

14. **Rate:** The rate quoted by tenderer shall remain firm and fixed until the completion of contract. If, rates are downward at any point of time during the period of rate contract, the rate contract holder will inform the same in writing immediately.

- (i) All rates quoted should be for ONE UNIT (figures & words both). Bids should be neatly typed. Rate calculation to be based on cost per IU for different strengths of vials in FVIII & FIX.
- (ii) No blank space should be left.
- (iii) Tenderer must ensure that the quoted rates are inclusive of GST as applicable. SGPGI will only accept the material which would be GST paid, if applicable. All rates quoted should be inclusive of all taxes including CGST & IGST as applicable.
- (iv) All rates quoted should be F.O.R. destination.
- (v) No escalation in rates (except Govt. levy/tax) would be permissible.
- (vi) Tenderer should take care that the rate and amount are written in such a way that interpolation is not possible.
- (vii) Tenderer should quote the rate in words & figures both.
- (viii) Alteration if any should be attested by the tenderer, otherwise tender will not be considered.
- (ix) If, rates are downward at any point of time during the period of rate contract, the rate contract holder will inform the same in writing immediately. More so, if the rates are not downward, the R/c holder will be required to submit an undertaking before issuance of supply order for the effect that the rates have not been downward.

15. **Award Criteria:** The contract will be awarded to the qualified bidder whose bid has been determined to be substantially responsive and has been determined to be the lowest evaluated bid (L-1), subject to the bidder agreeing to all terms & conditions of the tender. The Director, SGPGIMS shall have the right to empanel the other L-2, L-3, L-4, etc. responsive bidders who are qualified technically and willing to match L-1 rates. If after due processing, it is discovered that the quantity to be ordered is far more than what L-1 is capable of and unable to supply, then the quantity being finally ordered shall be distributed amongst the other qualified bidders who have given their unconditional consent to match L-1 rates, in a manner that is fair, transparent and equitable. Reasons of failure to supply the materials will be communicated by the L-1 firm (RC Holder) to the Institute timely. Repeated failure (two or three times) on supply part may amount to termination of rate contract for the product(s) and administrative action shall be taken for forfeiture of EMD and / or Performance Security along with other legal action as deemed appropriate.

16. Earnest Money Deposit EMD & Performance Security:

- (i) EMD of Rs. 36,00,500.00 (Thirty Six Lakh Five Hundred Only) in favour of "Director, SGPGIMS, Lucknow" shall be submitted online only as per details mentioned at 10 (1-A) above. EMD of the successful bidders will be retained, till the execution of rate contract, finalization of tender and submission of performance security.
- (ii) If the tenderer fails or neglects to observe or perform any of his/her obligations under the contract, it shall be lawful for the purchaser to forfeit the Earnest Money Deposit and performance security furnished by the tenderer.
- (iii) Performance Security @ 5% of estimated value for 01 year of approved item (s) but maximum to the limit of Rs. 1,00,00,000.00 shall be submitted by the successful bidders within 15 days from the date of award of rate contract in favour of "Director, SGPGIMS, Lucknow". The Performance Security shall be valid till period of rate contract. The EMD amount of Rs. 36,00,500.00 (Thirty Six Lakh Five Hundred Only) of eligible bidders for award of rate contract will be returned once the performance security is deposited by the firm/Rate Contract holder.
- (iv) The EMD of unsuccessful bidder shall be returned after finalization of rate contract/tender.

17. Change in Constitution of firm: Any change in the pattern of ownership of the contracting party will not nullify the provisions of the contract. The contract will devolve on the successor owners.

18. Fall Clause :If at any point of time during the execution of the contract, the contractor reduces the MRP / Sale Price or sells or offers to sell such stores, as are covered under the rate contract of the Institute, to any person or organization including the purchaser or any Central / State Government hospital / Institute at a price lower than the price chargeable under the rate contract of the Institute. He/she shall forthwith notify such reduction in MRP or sale price or offer of sale to the purchaser and the price payable under the contract for the store supplied after the date of coming into force of such reduction in MRP or sale price or offer of sale shall stand correspondingly reduced. Variation, if any, will be governed by the terms & conditions as enumerated in proposed rate contract.

19. Inspection and sampling at the consignee's end:

- (i) After the receipt of the consignment, the demanding officer will draw a sample out of each consignment and will send it for testing at one of the approved testing laboratories/user departments. If the sample/samples is/are found not of standard quality, the consignment shall be rejected. If the product is found to be not of standard quality for any of the above-mentioned reasons, the total cost of laboratory test will be recovered from the supplier. Where there are visible and obvious defect in the consignment, it shall be rejected.
- (ii) All rejected stores shall in any event remain and will always be at the risk of the contractor immediately on such rejection.
- (iii) Purchaser reserves the right to depute persons as may be designated by him to visit the premises of the manufacturers for ensuring that GMP(s) are observed by the



- manufacturers. It is also open to the purchaser to send persons as may be designated by him to inspect stores and draw samples from there before dispatch of consignment.
- (iv) In case of rejection of stores, the supplier will have to replace the entire quantity or make full payment of entire consignment against the particular invoice irrespective of the fact that part of the supplied stores may have been consumed.

## **20. Penalty Clause:**

- (a) **Non-execution of supply order** - The contract will be awarded to the qualified bidder whose bid has been determined to be substantially responsive and has been determined to be the lowest evaluated bid (L-1), subject to the bidder agreeing to all terms & conditions of the tender. The Director, SGPGIMS shall have the right to empanel the other L-2, L-3, L-4, etc. responsive bidders who are qualified technically and willing to match L-1 rates. If after due processing, it is discovered that the quantity to be ordered is far more than what L-1 is capable of and unable to supply, then the quantity being finally ordered shall be distributed amongst the other qualified bidders who have given their unconditional consent to match L-1 rates, in a manner that is fair, transparent and equitable. Reasons of failure to supply the materials will be communicated by the L-1 firm (RC Holder) to the Institute timely. Repeated failure (two or three times) on supply part may amount to termination of rate contract for the product(s) and administrative action shall be taken for forfeiture of EMD and / or Performance Security along with other legal action as deemed appropriate. The failure in execution of supply order(s) in a stipulated period and in satisfactory manner on the part of L1 firm may also amount to termination of rate contract for the product(s) and administrative action shall be taken for forfeiture of EMD and / or Performance Security along with other legal action as deemed appropriate.
- (b) **Late delivery clause** - The date & time of the delivery as stipulated in the supply order shall be deemed to be the essence of the contract and delivery must be completed no later than the date(s) as specified in the supply order. A penalty @ 1% per week will be imposed, if supply is delayed in part or full, subject to maximum of 10% of the total value of stores ordered. Extension in delivery period will only be permissible under the force majeure conditions for which specific extension must be obtained from the "Director, SGPGIMS, Lucknow " before the date of delivery in store.
- (c) **Non production of item** — Difference in the value between existing source and source from where supplies are being obtained for remaining tendered / ordered quantity will be recovered from the billing agency, subject to a minimum recovery / penalty of Rs 5000.00 (rupees five thousand) only per product irrespective of any reason.
21. **Items nearing expiry:** The items supplied nearing expiry and / or if not consumed, will be intimated at least three months in advance and will have to be replaced at his / her cost. Slow moving items may be asked for replacement with other approved items at the discretion of Institute.

22. **Disputes and Arbitration:** All disputes or differences arising during the execution of the contract shall be resolved by mutual discussion failing which the matter will be referred to the Director (SGPGIMS, Lucknow) for arbitration whose decision shall be the final binding on the contracting parties.

23. **Laws governing the contract:**

- (i) This contract shall be governed by the laws of Uttar Pradesh, India.
- (ii) The Courts of Lucknow shall alone have jurisdiction to decide any dispute arising out of or in respect of the contract.
- (iii) Terms and expressions not there undefined shall have the meaning assigned to them, if any, in the Indian Sale of Goods Act, 1930 or the Indian Contract Act, 1872 or the General Clauses Act, 1897 as amended from time to time.

24. **Terms of payment:**

- (a) 100% payment shall be made on receipt of goods in satisfactory conditions and submission of bill (a) with the material/challan (b) Payment will be made on 30 days from the date of submission of bill, with early payment option facility to be enumerated in the supply order.
- (b) Bills not received in accordance with the instructions as required on challan / bill (mentioned above) will not be entertained processed for payment by the Institute.
- (c) The part supplies are accepted for the sake of Convenience of Institute only but payment will be made by the SGPGI after completion of 100% supply.
- (d) The Institute retains the right of returning (to the supplier/s) any item in any quantity that helps to manage the inventory in most economical manner. The value of returned goods would be adjusted in any possible manner that suits the need of the Institute.
- (e) Bill in quadruplicate and pre-receipted must be submitted along with challan at the time of supply of the material at SGPGI stores. You are advised to comply this point very strictly to avoid any delay in release of the dues. Further you must ensure uninterrupted supply and change of billing agency will no way affect the supply schedule. The batch number and date of expiry must be mentioned in bill & challan.

25. **Any variation-**In the prices detected at any point of time the sole responsibility would rest with the firm and shall invite necessary action such as recovery and administrative action as deemed proper.

26. In view of the notification issued by the Ministry of Health & Family Welfare, Government of India, Gazette Notification no. SO 1468 (E) dated 6.10.2005 and GSR 627 (E) dated 7.10.2005, it would be sole responsibility of the Rate contract holder to comply with the applicable rules and regulations from time to time.

27. SGPGI will entertain only direct correspondence from RC holder.



28. **Termination of Contract:** In case any party (Institute or the company) wants to withdraw from the rate contract, it can do so after giving 03 (three) months notice in writing.
- (d) **Delivery period:** Normally, the delivery period would be within 04 weeks from the date of issuance of supply order. However, it may be less than this period depending upon the urgency if any. Institute will be free to procure item from L-2 or any other firm in case Rate Contract holder is unable to supply as per delivery period mentioned in supply order and the difference amount will be adjusted from R/c holder from upcoming invoice or from security money pledged with Institute.
29. Inter hospital transfer of factor, if required, must be completed within 03 days on receipt of instruction from State Nodal Officer/SGPGI.
30. Stamping on each vial "U.P. Govt. supply: Not for Sale" by the firm/vendor.
31. Cold chain maintenance, if indicated would have to be ensured during transportation, storage & distribution of vials by the vendor.
32. An objective scoring system would be used to assess the efficacy and safety among various CFC products.
33. Final order for various CFC (type and quantity) will be provided by the concerned committee constituted for the purpose and as per the directives from NHM/Govt.



Dr. Anil Kashyap  
State Nodal Officer  
for Hematophilia Program &  
Hep. Dept. of Hematology  
SGPGI, Lucknow-226015

**CERTIFICATE TO BE SUBMITTED TO****S.G.P.G.I.M .S. Lucknow**

(To be submitted in Original)

To,

The Director,  
Sanjay Gandhi Postgraduate Institute of Medical Sciences,  
Raebareli Road,  
Lucknow – 226 014

Sub: Tender Enquiry no: PGI / \_\_\_\_\_ dated \_\_\_\_\_

Sir,

I / We have gone through the terms & conditions laid down in the tender documents and accept the same. I am / we are submitting technical bid enclosing the documents as per details given below:

**(Essential Documents)****CHECKLIST****PART (A)**

Sl. No.	Name of Document	Pages (From)	Page (To)
1.	Cost of Tender document Rs. 29,500.00 (Rs. 25,000/- for tender fee + Rs. 4,500/- for GST) downloaded from e-tender portal (Non-refundable)		
2.	EMD of Rs.36,00,500.00 (Thirty Six Lakh Five Hundred only) for Anti-Hemophilic Factors (Refundable)		
3.	Average Annual Turnover Manufacturer/Bidder of Rs. 5.00 crore during last 03 years i.e. 2019-20, 2020-21, 2021-22.		
4.	Turnover for the year of F.Y. 2021-22 should be Rs. 5.00 crore		
5.	WHO-GMP Certificate		
6.	Self-Attested copies of evidence of supply the tendered products to countries.		
7.	Experience of 03 years in marketing & manufacturing. But, this shall not be applicable in case of new drug for which document must be attached.		
8.	Import License issued by Drug Controller General of India and DGS&D		
9.	Non-Conviction Certificate issued by State Drug Controller		
10.	Affidavit for non-blacklisting		
11.	Manufacturer or Importer Certificate/Declaration		
12.	Self-Attested copy of GST return		
13.	Self-declaration on Rs. 10.00 Non-Judicial Stamp paper duly notarized about lowest rates.		
14.	List of procurement agencies of repute to whom supply was made within 12 months		
15.	Notarized affidavit for no-relation with the person authorize to evaluate technically		
16.	Institutional Price list of company		
17.	Evidence of proof of Import for last 03 years		



18.	Proof for 'New Drug' category according to The Gazette of India and Import License issued by Directorate General of Health Services (DGHS) Central Drugs Standard Control Organization, Govt. of India		
19.	Self-Attested copies of USFDA/Research Molecule Certificate		
20.	Attested copy of Drug Manufacturing License from State Drug Controller		

#### **PART-B**

**Product catalogue for the items quoted in the tender. All the related documents which are needed for the items quoted in the tender.**

**(A)** The Bidder should have to give the details of the CEO (MD), Chairman with the Authorized Signatory of the tender Bid) such as:

- 1) Name
- 2) Tel. No.
- 3) E-mail ID,
- 4) Address

**(B)** It is certified that each and every page of the tender document are serially numbered, duly signed by me and the information furnished in tender document is true and correct to the best of my knowledge and belief.

Yours faithfully,

SEAL OF THE  
TENDERER

Signature Name Designation  
Name of company (Tenderer)  
Address  
Telephone No. Mobile No.  
Fax No./E-mail:



Dr. Anil Kumar  
Medical Officer  
Hemophilia Program &  
Dept. of Hematology  
CIPHS, Lucknow-226014

**Annexure- I****MANUFACTURING & MARKETING CERTIFICATE**

This is to certify that M/s \_\_\_\_\_ are holding valid manufacturing license No. \_\_\_\_\_ Dated \_\_\_\_\_ of the State and they are manufacturing the following products since the last three years.


It is further certified that the following products are also being marketed for last three years.

The Products are as follows:

Sl. No.	Name of Product (Generic in Nature)	Specification	Size

**Note:**

1. This certificate is to be signed by the Drug Controller of State. Certificate issued by inspector of Drugs/Drugs Inspector will not be accepted unless their authorization by the State Drug Controller to this effect is supported with documentary proof.
2. In case of 'New Drug' category according to The Gazette of India and Import License issued by Directorate General of Health Services (DGHS) Central Drugs Standard Control Organization, Govt. of India, the submission of 03 years Import Proof/Bill of Entry and Manufacturing & Marketing certificate shall not be applicable. But, the proof of 'New Drug' must be attached.



Dr. Rajesh Kashyap  
Nodal Officer  
Hemophilia Program &  
Dept. of Hematology  
ICMR, Lucknow-226015

Dated:

Signature and seal of  
Drug Controller of the State



**Annexure- II****Detail of the items quoted in the Technical Bid**

Sl, Tender item Sl. No.	Name of Item as in the Tender List	Specification of quoted items	Brand Name	Name of Agency for Quality Certification. e.g. US-FDA, WHO GMP etc.	Documentary Evidence of Prevailing Rate Contract of AllIMS, New Delhi Attached (Yes/No) If Yes, Page No.	
1	2	3	4	5	6	7

**Note:**

1. Tender list serial no. of the item should be the same serial no. as detailed in item list of tender document.
2. Use separate sheet in the same format in case of need of more space.
3. Any product other than listed in tender enquiry can be quoted in separate sheet in same format.



Medical Officer  
Hemophilia Program &  
Dept. of Hematology  
AllIMS, New Delhi-110029

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**Annexure- III**

**Format of BOQ**

**FORMAT OF BOQ**

Order Inviting Authority: Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Name of Work: ANTI-HEMOPHILIC FACTORS

Contract No.: PGI/MM/HEMOPHILIA/2022-23 (I...../JDMM/2022-23)

Name of the bidder/Bidding firm/Company:

PRICE SCHEDULE (This BOQ template must not be modified/replaced by the bidder and the same should be uploaded after filling the relevant columns, else the bidder is liable to be rejected for this tender. Bidder are allowed to enter the bidder name and Values only)

NUMBER #	TEXT #	NUMBER #	NUMBER #	NUMBER #	NUMBER #	NUMBER #	NUMBER #	NUMBER #	TEXT #
Sl. No.	Item Descriptions	Quantity	Units	BASIC RATE (In Figure to be entered by the bidder in Rs. P.)	GST (If applicable in Percentage)	GST AMOUNT In Rs. P.	TOTAL AMOUNT Excluding GST in Rs. P.	TOTAL AMOUNT Including GST in Rs. P.	TOTAL AMOUNT in Words
1	2	3	4	5	6	7	8	9	10
1	Anti-Hemophilic Factors (PGI/MM/HEMOPHILIA/2022-23)								INR Zero Only
1.01	FVIII with vwf (250 IU, 500 IU)	1.00	IU	0.00	0.00				INR Zero Only
1.02	Plasma Derived FIX (500-600 IU, 1000-1200 IU)	1.00	IU	0.00	0.00				INR Zero Only
1.03	Recombinant FVIII (250 IU, 500 IU, 1000 IU, 1500 IU)	1.00	IU	0.00	0.00				INR Zero Only
1.04	Recombinant FIX (500 IU)	1.00	IU	0.00	0.00				INR Zero Only
1.05	Extended Half Life (EHL) Recombinant FVIII Pegylated (Rurioctocog Alfa Pegol) (500 IU, 1000 IU, 1500 IU & 2000 IU)	1.00	IU	0.00	0.00				INR Zero Only
1.06	Extended Half Life (EHL) Recombinant FVIII Glycopegylated (Turoctocog Alfa Pegol) (500 IU, 1000 IU, 1500 IU & 2000 IU)	1.00	IU	0.00	0.00				INR Zero Only
1.07	Extended Half Life (EHL) Recombinant FIX Glycopegylated (Nonacog Beta Pegol) (500 IU, 1000 IU & 2000 IU)	1.00	IU	0.00	0.00				INR Zero Only
Total in Figures					0.00				
Quoted Rates in Words					INR Zero Only				



Dr. Neelash Kashyap  
State Nodal Officer  
Anti-Hemophilia Program &  
Hematology  
PGI, Lucknow-226012



**Annexure IV**

**SELF DECLARATION FOR LOWEST RATE**  
(on Rs 10.00 Non-judicial Stamp paper)

I, **(Name of the Signatory)**, **(Designation of the Signatory)** with M/s **(Name of the Company)**, do hereby certify that the rates quoted in the Tender No. PGI/MM/HEMOPHILIA/2022-23 are the lowest rates quoted to any Government Institute Hospital (State/Central). We also undertake that any downward revision including MRP during the period of rate contract will be passed on to the Institute.

Authorized Signatory

Designation

Seal

Date:

Place:



Anandesh Kashyap  
Nodal Officer  
Hemophilia Program &  
Dept. of Hematology  
PGI, Chandigarh-2022-23

**Annexure V****AFFIDAVIT**  
**(Notarized)****Reference Tender No. PGI/MM/HEMOPHILIA/22-23 Anti-Hemophilic Factors**

I, (Name of the Signatory), S/o Father's Name), (Designation of the Signatory) with (Name of the Company), with its office at (Address of the Head office of the Company), do solemnly affirm and declare as under:-

The bidder does not have any relation with the person authorized to evaluate technically or involved in finalizing the tender or will decide the use of tendered items

Place:

Date:

**Verification:**

Deponent

Verified that the contents of the above affidavit of mine are true and correct to the best of my knowledge Verified that the content and no part of it is false and nothing has been concealed therein. Verified at (Place), on this (Date) day of (Month) 2022.

Deponent



Dr. Rajesh Kashyap  
Joint Nodal Officer  
Anti-Hemophilia Program &  
Trans. Dept. of Hematology  
PGI, Chandigarh-202022



## Annexure-VI



**Sanjay Gandhi Post Graduate Institute Of Medical Sciences,**  
**Raebareli Road, Lucknow-226014**  
Tele: 0522-2494038 e-mail: [jdmm@sgpgi.ac.in](mailto:jdmm@sgpgi.ac.in)

### **MATERIALS MANAGEMENT DEPARTMENT**

Dated:

Ref: PGI/MM/HEMOPHILIA/22-23/

To,

#### **Sub: Annual Rate contract for supply of Anti-Hemophilic Factors**

Dear Sirs,

In reference to tender bid for above-mentioned items, your products as per enclosed **Annexure** is/are being covered under Annual Rate Contract. The terms and conditions to govern the Annual Rate Contract are as follows:

The award of rate contract is not linked to the procurement style opted by Institute during the entire period of rate contract. Any item under rate contract may be procured through supply order. Mode of procurement and inventory management of any item may be changed at any point of time.

1. (a) **PROCUREMENT ON SUPPLY ORDER BASIS:** - Supply of material is covered under this rate contract may increase or decrease. It will be made available on the basis of written supply order with terms and conditions as enumerated therein. It will be the responsibility of supplier to have an access with SGPGI to maintain the optimum inventory level. This has been decided to tide over the problem of over stocking including near expiry / slow moving / non moving inventories, for which following mechanism will be observed:-
- (i) Besides having liasoning with end user, you will be allowed to have access to computerized system to know the consumption pattern / reports of the items concerned.
  - (ii) Stock in hand position at Central SGPGI Store and peripheral sub stores can also be provided on demand.
  - (iii) Access to SGPGI stores is allowed to know the status of expiry / slow moving / non-moving products.
  - (iv) The company will own the responsibility of overstocking & expiry.
  - (v) The company will take all preventive measures and will keep informed Joint Director (MM) and State Nodal Officer in writing about any specific item/quantity mentioned in supply order that may lead to overstocking or expiry.
  - (vi) In case of any difficulty in getting the feedback from Central stores, you may contact JD (MM) / Director.
  - (vii) The Institute has the right to switch over from supply order based procurement to consignment / utilization based procurements also.
  - (viii) You will appreciate that any loss of material is going to be a national loss. Please keep informed about such items asked for supply but in fact not required by the users. In case of any difficulty in getting the feedback from SGPGI stores, you may contact JD (MM) / State Nodal Officer/ Director.

b) **PROCUREMENT ON CONSIGNMENT/UTILIZATION BASIS:-** All approved items on consignment / Utilization basis must be made available in sufficient quantity to cater the whole need of the Institute, Lead time for replenishment of such stocks will be 48 to 72 hours. It will be communicated by telephone, fax or e-mail to you or your authorized distributor.

2. **PERIOD OF VALIDITY:-** The Rate Contract will be valid for a period of 02 (two) years on yearly renewal basis subject to satisfactory performance of previous years. The rate contract may be extended for a period of 3 months after the expiry of 02 years or till the finalization of new rate contract whichever is earlier, if required.

3. **EMD & PERFORMANCE SECURITY:** -Please submit Performance Security @ 5% of estimated value for 01 year of approved item (s) but maximum to the limit of Rs. 1,00,00,000.00 (Rs. One Crore Only) within 15 days from the date of award of rate contract in shape of Bank Guarantee in favour of "Director, SGPGIMS, Lucknow " payable at Lucknow from any nationalized bank / scheduled bank. The Bank Guarantee shall be valid till period of rate contract.

The EMD amount of Rs. 36,00,500.00 (Rs. Thirty Six Lakh Five Hundred only) of eligible bidders for award of rate contract will be returned once the Bank Guarantee is deposited by the firm/Rate Contract holder. The EMD of unsuccessful bidder shall be returned after finalization of rate contract/tender

4. **TAXES AND DUTIES:** -Rates are inclusive of all taxes including GST (SGST & CGST), etc as applicable. Any price variation due to Govt. levies will be settled accordingly. Other charges like banks charges, postage, freight, etc. will be borne by your company.
5. **PRICES:** -Rates are F.O.R. destination basis i.e. Stores, SGPGIMS, Lucknow. No escalation in rates except Govt. levy / tax would be permissible. If at any point of time or during the execution of the contract, the contractor reduces the sale price including MRP or sells or offers to sell such stores, as are covered under the rate contract, to any person / organization including the purchaser or any department of Central / State Government / Quasi governed at a price lower than the price chargeable under the contract, he / she shall forthwith notify such reduction of sale or offer of sale to the purchaser and the price payable under the contract for the stores supplied after the date of coming into force of such reduction or sale or offer of sale shall stand correspondingly reduced.
6. **ROAD PERMIT:** -It would be the sole responsibility of the supplier to affect the door deliveries at his / her own. Institute will neither own any responsibility for clearance of goods from any road, rail, postal, air terminals nor any machinery of SGPGI would be allowed for this purpose.
7. **DELIVERY:** -Supplied material should have ordinarily minimum shelf life of 75% at the time of supply. Batch number and expiry date must be mentioned on face of the bill. Stores supplied through courier, post etc may be received under the sole responsibility of supplier regarding quantity, specification and breakage.
8. **DEFECTIVE INVENTORY:** -Stores/User department/Management Committee of the Institute will be the sole authority to declare inventory as defective either at the time of receiving the goods or after the use of goods. Cost of such defective inventory will be recoverable from forthcoming bill of the supplier or replaced with any other approved stocks, failing which contract may be terminated.
9. **PENALTY CLAUSE:-**
- (a) **Non-execution of supply order** - The Director, SGPGIMS shall have the right to empanel the other L-2, L-3, L-4, etc. responsive bidders those are qualified technically and willing to match L-1 rates. If after due processing, it is discovered that the quantity to be ordered is far more than what L-1 is capable of and unable to supply, then the quantity being finally ordered shall be distributed amongst the other qualified bidders who have given their unconditional consent to match L-1 rates, in a manner that is fair, transparent and equitable. Reasons of failure to supply the materials will be communicated by the L-1 firm (RC Holder) to the Institute timely. Repeated failure (two or three times) on supply part may amount to termination of rate contract for the product(s) and administrative action shall be taken for forfeiture of EMD and / or Performance Security along with other legal action as deemed appropriate. The failure in execution of supply order(s) in a stipulated period and in satisfactory manner on the part of L-1 firm may also amount to termination of rate contract for the product(s) and administrative action shall be taken for forfeiture of EMD and / or Performance Security along with other legal action as deemed appropriate.



- a. **Late delivery clause** - The date & time of the delivery as stipulated in the supply order shall be deemed to be the essence of the contract and delivery must be completed not later than the date(s) as specified in the supply order. A penalty of 1 % of the ordered value of order per week will be imposed on delayed supply subject to the maximum of 10% of the total value of order. Extension in delivery period will only be permissible under the force major conditions for which specific extension must be obtained from the HRF before the date of delivery in JD(MM) office.
- b. **Non production of item** - Difference in the value between existing source and alternative source from where supplies are being obtained for remaining tendered quantity will be recovered from the billing agency, subject to a minimum recovery / penalty of Rs 5000.00 (rupees five thousand) only per product irrespective of reasons.

**10. INFORMATION REQUIRED ON CHALLAN IBILL:-**

- (a) Supply order will be released and you may execute the supplies directly or through your authorized distributor. Challan must always mention the following:
- I. Name of the item as it was mentioned in supply order.
  - II. Brand name of the item as it is mentioned in the product literature of the company.
  - III. Size of the item.
  - IV. Supply order number.
  - V. Supply order date.
  - VI. Date of manufacturing
  - VII. Date of expiry.
  - VIII. Batch number.
  - IX. Quantity of each item.
  - X. **Challan must be endorsed by the security personnel at the SGPGI main gate / or end user. The endorsement must clearly state the date of entry of the material.**

- (b) Bill must always mention the following:-

- I. Name of the item as it was mentioned in supply order.
- II. Brand name of the item as it is mentioned in the product literature of the company.
- III. Size of the item.
- IV. Supply order number.
- V. Supply order date.
- VI. Date of manufacturing
- VII. Date of expiry.
- VIII. Batch number.
- IX. Quantity of each item.
- X. Value of each item
- XI. Total value of the bill
- XII. The amount of GST to be paid by the supplier.

**11. Replacement of near expiry / slow moving / non-moving items:** - It will be responsibility of supplier to get status of slow / non-moving inventory for replacement purposes from Central store on quarterly basis or at a higher frequency. If company fails to replace such slow moving / non-moving stocks in time, Institute will retain the right to identify such stocks any time during the contract period and return the same to the company. Cost of such returned inventory will be recoverable from forthcoming bill of the supplier or replaced with any other approved stocks, failing which contract may be terminated.

**12. Release of EMD**

- I. The Institute will return EMD of successful bidders once performance security is deposited by the firm.
- II. The bidders who has/have not awarded Rate Contract can take their EMD immediately after finalization of Rate Contract after due correspondence.

**13. PAYMENT:-**

- (a) 100% payment shall be made on receipt of goods in satisfactory conditions and submission of bill (a) With the material / challan (b) Payment will be made within 30th days from the date of submission of bill, with early payment option facility to be enumerated in the supply order.
- (b) Bills not received in accordance with the instructions as required on challan / bill (mentioned above) will not be entertained or processed for payment by the Institute.
- (c) The part supplies are accepted for the sake of convenience of patients only but payment will be made by the Institute after completion of 100% supply.
- (d) The Institute retains the right of returning (to the suppliers) any item in any quantity that helps to manage the inventory in most economical manner. The value of returned goods would be adjusted in any possible manner that suits the need of the Institute.
- (e) Bill in quadruplicate and pre-receipted payment must be submitted along with copy of challan at the time of supply of the material at Central stores. You are advised to comply this point to avoid any delay in release of the dues. Further, you must ensure uninterrupted supply.

**14. Any variation** in the prices detected at any point of time, the sole responsibility would rest with the firm and shall invite necessary action such as recovery / administrative action as deemed proper.

**15. Termination of Contract** - In case any party (Institute or the company) wants to withdraw from the rate contract, it can do so after giving 03 (three) months notice in writing.

**16.** However, Rest terms and conditions as detailed in tender documents would be applicable.

**17.** In view of the notification issued by the Ministry of Health & Family welfare, Government of India Gazette Notification no SO 1468 (E) dated 06.10.2005 and GSR 627 (E) dated 07.10.2005; it would be sole responsibility of the Rate Contract holder to comply with the applicable rules and regulations from time to time.

**18.** Material Management Department will entertain only direct correspondence from the RC Holder.

**19.** It would be responsibility of the Rate Contract holder to submit the undertaking during currency of contract by 1<sup>st</sup> week of every month to the effect that their prices have not come down during the proceeding or prevailing month.

**20.** Please send us your acceptance duly signed and stamped on duplicate copy of this rate contract as token of your acceptance before execution of the first supply order and also submit the performance security.

**21.** Rest terms & conditions will be applicable, as mentioned in notice inviting tender and supply order.

**22. The bidder shall provide the details of agents who will be responsible for Inter Hospital Transfer. It is the responsibility of the bidder to ensure a proper Supply chain for the transfer of CFC.**



Dr. Rajesh Kashyap  
State Nodal Officer  
Hemophilia Program &  
Trans. Dept. of Hematology  
ICFMR, Lucknow-226014



## Annexure-VII

To,  
The Director  
Sanjay Gandhi P G I MS.,  
Rae Bareilly Road,  
Lucknow

Reg: Tender Enquiry no: PGI/MM/HEMOPHILIA/22-23 – Anti-Hemophilic Factors

Subject: Acceptance of Terms and Conditions of Rate Contract

Sir,  
I have gone through the conditions laid down in the tender documents.

I hereby accept the above proposed terms and conditions of the rate contract (Annexure-VI) in case of the same is being awarded to my firm against quoted items in this tender documents.

(Authorized Signatory)

Date:

Place:



Dr. Rajesh Kashyap  
Nodal Officer  
Anti-Hemophilia Program &  
Dept. of Hematology  
PGI, Lucknow-226003

**Annexure-VIII**

To,  
The Director  
Sanjay Gandhi P G I M S.,  
Rae Bareli Road,  
Lucknow

**Reg: Tender Enquiry no: PGI/MM/HEMOPHILIA/22-23 - Anti-Hemophilic Factors**

Sir,

I have gone through the conditions laid down in the tender documents.

I hereby offer to supply the items mentioned in Price Bid at the rates quoted therein. I hereby declare to supply the material duly paid with GST, if applicable. I agree to hold this offer open for the period of rate contract from the date of issuance of Rate Contract, if awarded.

(Authorized Signatory)

Name

Seal




Dr. Rajesh Kashyap  
State Nodal Officer  
Hemophilia Program &  
Hod, Dept. of Hematology  
PGIMS, Lucknow-226001



### Specifications of Anti-Hemophilic Factors (AHF) for Tender for hemophilia patient

S.No.	Item	Strength per vial	General Specification	Additional Requirements
1.	FVIII with VWF	250 IU, 500 IU	<ol style="list-style-type: none"> <li>1. Safety and efficacy standards as per World Federation Hemophilia (WFH) guidelines for CFC assessment. Specify purity or specific activity of factor. An objective scoring system would be used to assess.</li> <li>2. Mention Pathogen inactivation/viral reductions method used for enveloped and non-enveloped viruses</li> <li>3. Manufacturer to submit "Product Assessment. Questionnaire" provided herewith.</li> <li>4. Do you have plasma master file (for plasma derived CFC). Submit proof of global plasma safety certification.</li> <li>5. No human and animal derived proteins should have been used during manufacture formulation.</li> <li>6. Undertaking for capacity to provide consistent supply of CFC as per approx. annual requirement (FVIII 10 Million IU and FIX 2.5 Million IU approx) Mention total number of production sites/units for pd-CFC.</li> <li>7. Final order for various CFC (type and quantity needed to be provided by the concerned committee constituted for the purpose and as per the directives from NHM/Govt.</li> </ol>	<ol style="list-style-type: none"> <li>1. Provide package insert of plasma and recombinant products. Mention about the type &amp; quantity of diluents required and final reconstituted infusion volume. Mention dissolution time.</li> <li>2. User list of hospitals in Government sectors with supply orders.</li> <li>3. Product performance in relation to efficacy &amp; safety through clinical studies and performance certificate from other states/government agencies.</li> <li>4. Mention pharmacovigilance. Submit batch release testing of product by NIB India. Mention about any adverse report/reaction or blacklisting of product/vendor in the country.</li> <li>5. Mention shelf life and stability at room temperature for CFC.</li> <li>6. Rate calculation to be based on cost per IU for overall comparison including for different strengths vials in FVIII &amp; FIX.</li> <li>7. Price of plasma CFC will be compared with plasma CFC and similarly recombinant CFC would be compared with recombinant products.</li> <li>8. Stamping on each vial "UP Govt. supply: Not for sale" by the vendor.</li> <li>9. Inter hospital transfers as and when required to be done by the vendor at his cost.</li> <li>10. Other terms and conditions as per government rules applicable intenders.</li> </ol>
2.	Plasma Derived FIX	500-600 IU, 1000-1200 IU		
3.	Recombinant FVIII	250 IU, 500 IU, 1000 IU, 1500 IU		
4.	Recombinant FIX	500 IU		
5.	Extended Half Life (EHL) Recombinant FVIII Pegylated (Rurioctocog Alfa Pegol)	500 IU, 1000 IU, 1500 IU, 2000 IU		
6.	Extended Half Life (EHL) Recombinant FVIII Glycopegylated (Turoctocog Alfa Pegol)	500 IU, 1000 IU, 1500 IU, 2000 IU		
7.	Extended Half Life (EHL) Recombinant FIX Glycopegylated (Nonacog Beta Pegol)	(500 IU, 1000 IU, 2000 IU)		

  
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# INFORMATION SUMMARY FROM CANDIDATE SUPPLIERS OF HEMOPHILIA PLASMA PRODUCTS

## 1) PLASMA RAW MATERIAL

### (A) PLASMA SUPPLIER

Name of supplier	Source or recovered	% first time donors	% repeat donors

### (B) DONOR EPIDEMIOLOGY

Name of supplier	HIV antibody positive donations		HCV antibody positive donations		HbsAg positive donations	
	per 10000 repeat donors	per 10000 new donors	per 10000 repeat donors	per 10000 new donors	per 10000 repeat donors	per 10000 new donors

### (C) REGULATORY STATUS OF PLASMA SUPPLIERS

Name	Frequency of internal audits performed by supplier, if any	Frequency of external audits performed by manufacturer, if any	Frequency of external audits performed by government authority, if any	Any other certification by a competent body

### (D) DONOR SELECTION - EXCLUSION CRITERIA (WHETHER CHECKED FOR AND WHAT ACTION)

Name	History of blood-borne infections (hepatitis/HIV, Etc.)	Intravenous drug abuse	High-risk sexual behaviour (male to male sex, prostitution, etc.)	Recipients of blood, tissues, etc.	Risky behaviour - tattoos, piercing, etc.	Medical procedures

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<b>(E) BLOOD/PLASMA SCREENING</b>						
Screening test	Name of kit - manufacturer	Regulatory status (USA/Europe)				
HbsAg						
HCV antibody						
HIV antibody						
HCV NAT (if any)						
HIV NAT (if any)						

<b>(F) QUALITY ASSURANCE OF TEST KITS</b>						
Describe any internal and external QA used by the collection agencies for their screening tests						

<b>(G) PLASMA MEASURES BY MANUFACTURER</b>						
Any inventory hold measures, etc.	Maximum number of donations in plasma pool	Testing of the plasma pool - serology, NAT, etc.	Estimate of viral load in plasma pool from viral incidence data			
			HIV	HCV	HBV	

<b>2) MANUFACTURING PROCESS</b>																			
The manufacturer is to include a copy of the licence to manufacture issued by the country where the facility is located and any other authority																			
<b>(A) CRITICAL STEPS</b> Here insert a flow chart of the manufacturing process, identify the crucial manufacturing steps and list their related in-process controls (IPCs)																			
<b>(B) VIRAL REDUCTION</b> List dedicated viral reduction steps Validated log <sub>10</sub> elimination for 1. HIV (actual virus) 2. HCV (specify model e.g., BVDV, etc.) 3. HBV (specify model) 4. HAV (actual virus or specify model) 5. Parvovirus B19 (specify model) Estimated residual risk per vial of product from plasma pool viral load and validated viral elimination data, for 1. HIV 2. HCV 3. HBV																			
<b>(C) PROCESS CONSISTENCY</b> List in-process controls (IPCs) identified in 2(a) for three chronologically sequential batches of the product manufactured at the scale used for the marketed form manufactured within the last 18 months.																			
In-process controls	<table border="1"> <thead> <tr> <th>Batch - 01</th> <th>Batch - 02</th> <th>Batch - 03</th> </tr> </thead> <tbody> <tr> <td>IPC-1</td> <td></td> <td></td> </tr> <tr> <td>IPC-2</td> <td></td> <td></td> </tr> <tr> <td>IPC-3</td> <td></td> <td></td> </tr> <tr> <td>IPC-4</td> <td></td> <td></td> </tr> <tr> <td>IPC-5</td> <td></td> <td></td> </tr> </tbody> </table>	Batch - 01	Batch - 02	Batch - 03	IPC-1			IPC-2			IPC-3			IPC-4			IPC-5		
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IPC-5																			

*[Handwritten signature]*

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 State Nodal Officer  
 Hemophilia Program  
 State Dept. of Hematology  
 F-10/1, Lahore-54000

**(D) STABILITY AND SHELF LIFE**

Include the data for the potency (FVIII or FIX) of the product measured during the requested shelf life, at the temperatures sought in the application.

Potency IU/mL (mean+sd)	At release	3 months	6 months	12 months	24 months

Include the data for the product's potency after reconstitution as specified, at 2, 8, and 24 hours after reconstitution

**3) FURTHER PRODUCT INFORMATION**

**(A) OTHER MARKETS**

List the other markets where the product is available, its history in these markets, volumes supplied, and related marketing authorizations from licensing bodies.

**(B) CLINICAL STUDIES**

Summarize clinical trials used to demonstrate product efficacy, referring to the authorizations from other markets listed in 3(a). Manufacturers should comment on their endorsement or otherwise on the EMEA's *Note for Guidance on the clinical investigation of plasma derived FVIII and FIX products*, accessible from <http://www.emea.eu.int/pdfs/human/bpwg/019895en.pdf>.

**(C) ADVERSE EVENTS**

Describe manufacturer's system for receiving and reporting adverse events related to the product.

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