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CIN: U24233KL2007SGC021616

Essential Drugs Division
No. KMSCL/ED/39/2023

www.kmscl.kerala.gov.in
Date: 20.11.2023

NOTICE
(ANTI HAEMOPHILIA DRUGS)

Sub :- KMSCL - E-tender for the procurement of Anti Haemophilia Drugs for the year 2023-24 -Technical Bid Evaluation – defects noticed/status - Published - reg.

Ref :- E-tender No. KMSCL/ED/HAEM/RC/2023/014 Dated 11.09.2023.

Technical bids submitted in response to the e-tender referred above for the procurement of Anti Haemophilia Drugs for the year 2023-24 were opened on 07.10.2023 and scrutinized. The status is published below.

All the bidders are directed to verify the details of their offered items in the notice published.

The Complaints/suggestions/representations, if any, on this notice shall be submitted to the Tender Inviting Authority in writing on or before **12 noon on 24.11.2023**.

Sl. No	Drug Code	Drug Name	Strength	Unit	Defects Noticed
Bid No. 1		M/s. Takeda Biopharmaceuticals India Pvt. Ltd, Gurgaon			
1	D12058	ANTI HAEMOPHILIC FACTOR VIII with VON WILLIBRAND FACTOR	250 IU (contains Factor VIII 250 IU along with minimum 50% of VWF)	1 No	1. Notary attested copy of relevant documents on traceability from the donor/ raw material to finished products and vice versa not submitted separately for the quoted products. 2. The firm have not submitted NIB test reports
2	D12024	HUMAN ANTI HAEMOPHILIC FACTOR IX	500 IU / 600 IU	1 No	
3	D12025	FACTOR VIII INHIBITOR BYPASSING AGENT (FEIBA)	500 U	1 No	

Sl. No	Drug Code	Drug Name	Strength	Unit	Defects Noticed
					<p>for all the batches mentioned in Annexure VIII, & Annexure IV for the year 2019-20, 2020-21, and 2021-22 for the quoted items.</p> <p>3. For D12058- ANTI HAEMOPHILIC FACTOR VIII with VON WILLIBRAND FACTOR, the total no. of batches manufactured for the year 2021-22 is mentioned as 11 in Annexure VIII and details of 12 batches is mentioned in Annexure IV.</p> <p>4. For D12024- HUMAN ANTI HAEMOPHILLIC FACTOR IX, the total no. of batches manufactured for the year 2021-22 is mentioned as 15 in Annexure VIII and details of 16 batches is mentioned in Annexure IV.</p> <p>5. The firm had not submitted three year track record of supplying the quoted items in at least three out of seven major institutions listed as per Clause no 5.2.8.1& 5.2.8.2of the tender document. (The details in Annexure IX and notary attested documents to prove the supply of quoted items).</p>
Bid No. 2		M/s. Novo Nordisk India Private Limited, Bangalore			

Sl. No	Drug Code	Drug Name	Strength	Unit	Defects Noticed
1	D12057	ANTI HAEMOPHILIC FACTOR VII	1 mg (50,000 IU)	1 No	<p>1. Notary attested copy of relevant documents on viral detection tests performed in the raw materials and in finished products, the statement on viral detection tests performed in Annexure VI are not submitted. If not required for the offered product documentary evidence to prove the claim to be submitted</p> <p>2. Details of batches tested at NIB not mentioned in the Annexure VIII submitted. If not required for the offered product documentary evidence to prove the claim to be submitted.</p> <p>3. The firm had not submitted three year track record of supplying the quoted items in at least three out of seven major institutions listed as per Clause no 5.2.8.1 & 5.2.8.2 of the tender document. (The details in Annexure IX and notary attested documents to prove the supply of quoted items).</p>
Bid No. 3		M/s. Grifols India Healthcare Private Limited, Gurgaon			
1	D12058	ANTI HAEMOPHILIC FACTOR VIII with VON WILLIBRAND FACTOR	250 IU (contains Factor VIII 250 IU along with minimum 50% of VWF)	1 No	1. Notary attested copy of previous import licenses issued three years prior to date of notification of the tender for D12058 - ANTI HAEMOPHILIC
2	D12024	HUMAN ANTI HAEMOPHILIC FACTOR IX	500 IU / 600 IU	1 No	

Sl. No	Drug Code	Drug Name	Strength	Unit	Defects Noticed
					<p>FACTOR VIII with VON WILLIBRAND FACTOR 250 IU (license no - IL/BIO-000069) is not submitted.</p> <p>2. Strength of VON WILLIBRAND FACTOR is not mentioned in the Import license submitted for ANTI HAEMOPHILIC FACTOR VIII with VON WILLIBRAND FACTOR 250 IU (contains Factor VIII 250 IU along with minimum 50% of VWF).</p> <p>3. Notary attested copy of Valid Market Standing Certificate / Bill of lading /Sales invoices to prove that ANTI HAEMOPHILIC FACTOR VIII with VON WILLIBRAND FACTOR is being imported/Marketed by the bidder for the year 2019-20 and 2020-21 not submitted.</p> <p>4. Notary attested copy of Valid Market Standing Certificate / Bill of lading /Sales invoices to prove that HUMAN ANTI HAEMOPHILLIC FACTOR IX is being imported/Marketed by the bidder for the year 2019-20 not submitted.</p> <p>5. The number of batches mentioned in Annexure VIII does not match with</p>

Sl. No	Drug Code	Drug Name	Strength	Unit	Defects Noticed
					<p>the details of batches in Annexure IV submitted for all the quoted items.</p> <p>6. The notary attested copy of NIB test reports for the batches mentioned in Annexure IV not submitted for the quoted items.</p> <p>7. The firm had not submitted three year track record of supplying the quoted items in at least three out of seven major institutions listed as per Clause no 5.2.8.1 & 5.2.8.2 of the tender document. (The details in Annexure IX and notary attested documents to prove the supply of quoted items).</p> <p>8. Notary attested copy of relevant documents on traceability from the donor/ raw material to finished products and vice versa not submitted separately for the quoted products.</p>
Bid No. 4		M/s. Intas Pharmaceuticals Limited, Ahmedabad			
1	D12024	HUMAN ANTI HAEMOPHILLIC FACTOR IX	500 / 600 IU	1 No	1. Notary attested copy of relevant documents on traceability from the donor/ raw material to finished product and vice versa not submitted separately for the quoted product.

Sl. No	Drug Code	Drug Name	Strength	Unit	Defects Noticed
					<p>2. The number of batches mentioned in Annexure VIII does not match with the details of batches in Annexure IV submitted for the quoted item.</p> <p>3. The notary attested copy of NIB test reports for the batches mentioned in Annexure IV not submitted for the quoted item.</p> <p>4. The firm had not submitted three year track record of supplying the quoted item in at least three out of seven major institutions listed as per Clause no 5.2.8.1 & 5.2.8.2 of the tender document. (The details in Annexure IX and notary attested documents to prove the supply of quoted item).</p>

Sd/-
MANAGING DIRECTOR
KERALA MEDICAL SERVICES CORPORATION LTD.
(TENDER INVITING AUTHORITY)