TENDER NO. BMSIC/DRUGS/21-02

Check list - I: Evaluation sheet to be used for preliminary evaluation of technical bids

Company Name : - M/s NOVO NORDISK INDIA PRIVATE LIMITED . Total Number of Pages Submitted in bid documents: - 01 TO 294

Sl. No	SBD clause serial No	Descrption of the Clause/ Technical Eligibility Criteria as per SBD as mentioned in the Check List	Document/ fees submission status (Yes/ No)	Page number	Do the provided documents meet the eligibility criteria ? (Yes/ No)	Remarks
1	3. (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.	YES	294	YES	-
2	3.(b)	Bidder are 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 from any Scheduled/Nationalized bank payable at Patna as per following table :- S.N. No. of drugs quoted EMD Amount 1 Upto 5 drugs Rs1,00,000/- (One Lakh only) 2 For 6 to 10 Drugs Rs 2,00,000/- (Two Lakh only) 3 For 11 to 15 Drugs Rs 3,00,000/- (Three Lakh only) 4 For 16 to 20 Drugs Rs 4,00,000/- (Four Lakh only) 5 More than 20 Drugs Rs 5,00,000/- (Five Lakh only)	YES	72-75	YES	-
3	3.(c)	Documentary evidence of the constitution of the company/firm/Proprietorship 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.	YES	243-274	YES	-
4	3.(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.	YES	284	YES	-
5	3.(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.	YES	285-286	YES	-
6	3.(l)	Copies of the Audited Balance Sheet and Profit and Loss statement showing details of their annual average turnover not less than 25 Crores (Twenty-Five) for any three of the last four consecutive financial years (Auditor/CA certificate of turnover will not be accepted). Selfattested copies are to be submitted.	YES	62 & 66 & 70	YES	-
7	3.(m)	Copy of Income Tax Return for any three of last four Consecutive Assessment years should be submitted (self-attested).	. YES	212-214	YES	-
8	3.(p)	Copy of PAN Card of the bidder company should be submitted (self-attested).	YES	_	YES	FOUND IN ORIGINAL COPY
9	3.(q)	Copy of certificate of valid GST registration of the bidder company should be submitted (self-attested).	YES	90-92	YES	-

Archana Singh
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TENDER NO. BMSIC/DRUGS/21-02

Check list - II: Evaluation sheet to be used for preliminary evaluation of technical bids

Company Name:- M/s Novo Nordisk India Pvt. Ltd, Addess- M/s Novo Nordisk A/S, Novo, Alle, DK-2880 Bagsvaerd, Denmark
Corporate Address- Plot no. 32, 47-50, EPIP Area, Whitefield Bangalore 560066. Total Number of Pages Submitted in bid documents:- 294

Sl. No	SBD Clause serial No	Description of the Clause/ Technical Eligibility Criteria as per SBD, as mentioned in Check List	Document/ fees submission status (Yes/ No)	Page Number as numbered by BMSICL	Do the provided documents meet the eligibility criteria ? (Yes/ No)	Remarks
1	3.(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.**	Yes	284	Yes	
2	3.(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.	Yes	285-286	Yes	
3	3.(f)	Minimum three years old valid Manufacturing License of the product quoted with latest license renewal certificate.	Yes	104-145	Yes	
4		Approved product list as per the license issued for quoted drugs for minimum three years.	Yes	104-145	Yes	
5		Manufacturing License along with approved product list must be valid till the last date of the submission of tender.	Yes	104-145	Yes	
6		In Case of those drugs which are notified first time in IP 2014 then Manufacturing and Marketing license should be in any official compendium (USP/BP/IP) along with current valid License in IP in continuation.	NA	NA	NA	
7		Bidders shall submit self-attested copies of required manufacturing license and approved product list (as applicable) in support of above-mentioned condition and they are required to specify the quoted product in their approved product list by highlighting it.	NA	NA	NA	
8		Market standing certificate & Manufacturing certificate issued by the Licensing Authority as a Manufacturer for each drug quoted for the last 3 years (Certificate should be enclosed with list of items) except for the drugs falling under the category of 'New Drug' as defined by CDSCO (Central Drugs Standard Control Organisation). If permission in Form 46 from DCGI has been obtained, then the 3 years Manufacturing & Market standing clause will be relaxed. The provisions of Rule 122 E of Drugs and Cosmetics Act rule 1945 shall be applicable. **Explanation-** In case of Importers Permission in Form 45 from DCGI is required as Per Drugs & Cosmetics Act 1940 & Rules 1945.	Yes	235-237 (Market standing certificate) 142 (Form 45)	Yes	

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9		For all regulated products, the bidder should have at least two years of manufacturing and marketing experience of the particular items as a manufacturer for each regulated product quoted in the tender. However, this would not apply to regulated products which have been licensed by DCGI less than two years ago. A certificate from DCG (I) shall be required for all new regulated products to this effect.	**Yes**	**235-237**	**Yes**	
10		FFS (Flow Fill & Seal Process) Technology will be accepted wherever applicable.	**NA**	**NA**	**NA**	
11		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).	**NA**	**NA**	**NA**	
12		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 product in their approved product list by highlighting it.	**Yes**	**104-145**	**Yes**	
13	**3.(g)**	In case of Importer, the bidder (importer) firm must have minimum three years old 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 are being imported and sold in India by the bidder (Importer) firm minimum for Last three years. Import license must be valid on the last date of submission of tender.	**Yes**	**104-145**	**Yes**	
14	**3.(h)**	Bidder must have Market Standing Certificate (in India) of minimum three years issued by the concerned Licensing Authority from Drugs Control Department for the quoted product. Self-attested copies are to be submitted.	**Yes**	**235-237**	**Yes**	
15	**3.(i)**	Non-Conviction Certificate (NCC) issued by the concerned Licensing Authority from Drugs Control Administration of the state for last three years should be submitted. It should be not more than one year old. Self-attested copies are to be submitted.	**Yes**	**277-280**	**Yes**	
16	**3.(j)**	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. The GMP certificate must not be older than one year from 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.	**Yes**	**76-78 (GMP) 80-84 (COPP)**	**Yes**	

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17	3.(k)	Maximum Production Capacity Certificate (section wise) issued by concerned Licensing Authority form Drugs Control Department highlighting the quoted product section. Selfattested 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 said production (Importing) capacity shall be adequate for requirement laid in NIT. Importer will have also to submit Invoices/Evidence of import in items of said product with quantity details.	Yes	152-156	Yes	
18	3.(n)	The tenderer should give an affidavit (with stamp) sworn before 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.**	Yes	275-276	Yes	
19	3.(o)	List of item quoted in prescribed format as per **Annexure-III** duly signed.	Yes	289	Yes	
20	5.(k)	An Affidavit (with stamp) regarding acceptance of tender conditions to be submitted by the bidding firm as per **Annexure-IV.**	Yes	290-291	Yes	
21	5.(l)	Filled check list as per given **Annexure-VI** to be submitted at the time of uploading the bid.	Yes	18-19	Yes	
22	7.(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.	Yes	285-286	Yes	
23	10.(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.	NA	NA	NA	
24	2(d) Explanation	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. In extraordinary case the Managing Director has discretion to take decision. **Explanation-** In order to ensure procurement of the tendered drugs at the most appropriate and competitive rate, the bidders are directed to quote their lowest price as compared to the Rates provided to their respective Distributors/Dealers/ Wholesalers/Carrying and Forwarding Agents/Authorized depot sales point in the State of Bihar. A Notarized affidavit to this effect on a Rs 100/- Non-Judicial Stamp Paper should be submitted with the Bid in the prescribed format as mentioned in Annexure-X.	Yes	292-293	Yes	
25	_	**Annexure- IX** Performance Statement (for the period of last three years)	Yes	215-234	Yes	
26		**Production Capacity Statement (Self Declaration) ANNEXURE VIII**	Yes	287-288	Yes	

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TENDER NO. BMSIC/DRUGS/21-02

Check list - III: Evaluation sheet to be used for preliminary evaluation of technical bids

Company Name:- M/s Novo Nordisk India Pvt. Ltd, Addess- M/s Novo Nordisk A/S, Novo, Alle, DK-2880 Bagsvaerd, Denmark
Corporate Address- Plot no. 32, 47-50, EPIP Area, Whitefield Bangalore 560066. Total Number of Pages Submitted in bid documents:- 294

Sheet to be used for verification of product approval and market standing

Sl. No	NIT Sl. No	Name of the Quoted Drug		Pharmacopoeial Specification/ Strength		Pack Size		Dosage Form		Approval Details			Last 3yrs market standing certificate/ New Drug
		As per NIT	As per Approval	As per NIT	As per Approval	As per NIT	As per Approval	As per NIT	As per Approval	First Approval	Approved Upto	Approved in Brand /Generic Name	
1	8	Factor VII Injection	Eptacog Alfa- Activated, human Coagulation VII Activated (page no. 107)	Recombinant 1mg	Eptacog Alfa (activated), Human recombinant Coagulation factor VII activated 1 mg (50KIU) to be used with reconstitution solvent and Infusion kit. (NovoSeven and Novoseven Infusion kit/ Novoseven MixPro).	1mg/Vial 20 Vials/Box	Not mentioned	Injection	Injection	29.01.2015	31.12.2023	Generic	Submitted (page no. 235-237)

TENDER NO. BMSIC/DRUGS/21-02

Check list - IV: Evaluation sheet to be used for preliminary evaluation of technical bids

Company Name:- M/s Novo Nordisk India Pvt. Ltd, Addess- M/s Novo Nordisk A/S, Novo, Alle, DK-2880 Bagsvaerd, Denmark
Corporate Address- Plot no. 32, 47-50, EPIP Area, Whitefield Bangalore 560066. Total Number of Pages Submitted in bid documents:- 294

Sheet for verification of licence details

Sl. No.	NIT Sl. No	Name of the Drug as per NIT	Manufacturer		Importer		Validity		GMP/ WHO GMP/ COPP (Import)	
			Forms Number	Manufacturing license Number	Forms Number	Import license Number	From	To	From	To
1	8	Factor VII Injection	NA	NA	10	FF-15-92 26.03.2018	01.01.2018	31.12.2023	05.12.2019 10.01.2020	04.12.2022 (GMP) 09.01.2022 (COPP)

Note:- Assisted in technical evaluation in reference to letter no. BMSIC/40025/108-2021/820 dt 07.05.2021 on the basis of documents provided by BMSICL as check list II, III & IV. Provided checklist compiled with due deligence and care.Inspite, some inadvertent discreprencies could have been crept in. Humble request to all concerned to bring to the notice in due time if any discrepencies are observed for rectification.

25/5/2021