TENDER NO. BMSIC/DRUGS/20-14

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

Name of the Bidder : - M/s MYLAN LABORATORIES LIMITED **Total Number of Pages Submitted in bid document: - 01 TO 71**

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	62	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/Kits Rs1,00,000/- (One Lakh only) 2 6 to 10 drugs/Kits Rs 2,00,000/- (Two Lakh only) 3 11 to 20 drugs/Kits Rs 3,00,000/-(Three Lakh only)	YES	61	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	71	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	_	YES	FOUND IN ORIGINAL COPY
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	48	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 5 Crores (Five) 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.	YES	51 & 55 & 59	YES	-
7	3.(m)	Copy of Income Tax Return for any three of last four Consecutive Assessment years should be submitted (self-attested).	YES	65-67	YES	-
8	3.(p)	Copy of PAN Card of the bidder company should be submitted (self-attested).	YES	63	YES	-
9	3.(q)	Copy of certificate of valid GST registration of the bidder company should be submitted (self-attested).	YES	64	YES	-

Archana Singh
01/4/21

TENDER NO. BMSIC/DRUGS/20-14

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

Company Name:- M/s Mylan Laboratories Ltd, Address- F-4, F-12, MIDC, Malegaon, Tal. Sinnar, Nashik, 422113

Total Number of Pages Submitted in bid documents:- 71

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.**	No	No	No	Submitted in hard copy
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	47-48	Yes	
3	3.(f)	Minimum three years old valid Manufacturing License of the product quoted with latest license renewal certificate.	Yes	37-39	Yes	
4		Approved product list as per the license issued for quoted drugs for minimum three years.	Yes	41	No	First Product approved not submitted
5		Manufacturing License along with approved product list must be valid till the last date of the submission of tender.	Yes	37-41	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		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	45	Yes	
8		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.	NA	NA	NA	

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9		FFS (Flow Fill & Seal Process) Technology will be accepted wherever applicable.	NA	NA	NA	
10		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).	No	No	No	Not submitted
11		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	37-41	No	Not highlighted
12	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.	NA	NA	NA	
13	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.	NA	NA	NA	
14	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	Yes	46	Yes	
15	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	30-31	Yes	
16	3.(k)	Maximum Production Capacity Certificate (section wise) issued by concerned Licensing Authority form Drugs Control Department highlighting the quoted product section. 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 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	28-29	Yes	

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17	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	26-27	Yes	
18	3 (o)	List of item quoted in prescribed format as per **Annexure-III** duly signed.	Yes	36	No	**Date & issue of product approval not written**
19	5.(k)	An Affidavit (with stamp) regarding acceptance of tender conditions to be submitted by the bidding firm as per Annexure-IV.	Yes	22-23	Yes	
20	5.(l)	Filled check list as per given Annexure-VI to be submitted at the time of uploading the bid.	No	No	No	**Submitted in hard copy**
21	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	47-48	Yes	
22	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	
23	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	24-25	Yes	
24	5 (j)	PERFORMANCE STATEMENT as per **Annexure- IX** submitted with the bid document should be self-attested by the authorized signatory of the firm with official seal, wherever required.	No	No	No	**Not submitted Annexure- IX found in hard copy but order copy not submitted**
25	–	Production Capacity Statement (Self Declaration) **Annexure- VIII**	No	No	No	**Submitted in hard copy**

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TENDER NO. BMSIC/DRUGS/20-14

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

pany Name:- M/s Mylan Laboratories Ltd, Address- F-4, F-12, MIDC, Malegaon, Tal. Sinnar, Nashik, 422113
Total Number of Pages Submitted in bid documents:- 71

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			Manufacturing Certificate
		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	6	Tenofovir 300 mg (TDF)	Tenofovir Disoproxil Fumarate Tablets IP 300 mg	1. Each tablet contains Tenofovir Disoproxilfumarate 300 mg. 2. Number of tablets/capsules per container: 30 tablets/package. 3. Should be licensed under the provisions of Drugs and Cosmetics Act and Rules. 4. The product insert must indicate dosage form (tablet/capsule) and the drug content. The product should conform to standards of IP or any other pharmacopeia. 5. The label must indicate clearly the manufacturing and the expiry dates. General Specifications 1. Standard Shelf Life. at least 18 months at the place of dispatch to the Consignee. 2. Primary container: Suitable, Opaque Plastic Bottle to contain 30 tablets. It should be sealed with plastic plug/ diaphragm and should contain silicon packs, and should have a tightly fitting suitable screw cap or any other packaging subject to the approvals of the concerned authority based on which the license has been granted under the provisions of Drug and Cosmetic Act & Rules. 3. Label: It should be glazed label in accordance with the statutory requirements as per drug and cosmetic Act. The standard color of the label as approved by NVHCP should be used. Each label should have clearly marked as "Government of India supply, not for sale" on primary packaging. The packaging and labelling requirements must meet the GMP practices. 4. Each lot shall be tested in compliance with the pharmacopeia specifications by a designated laboratory before supply. The committee approved the specification of Tenofovir 300 mg (TDF).	Tenofovir Disoproxil Fumarate Tablets IP 300 mg	300 mg TDF	Each film coated Tablet Contains: Tenofovir Disoproxil Fumarate IP (300 mg)	300 mg	300 mg	Not mentioned	13.05.2020 page no. 40	Generic	03.08.2025 page no. 45

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TENDER NO. BMSIC/DRUGS/20-14

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

pany Name:- M/s Mylan Laboratories Ltd, Address- F-4, F-12, MIDC, Malegaon, Tal. Sinnar, Nashik, 422113
Total Number of Pages Submitted in bid documents:- 71

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	6	Tenofovir 300 mg (TDF)	25	25-NKD/89	NA	NA	04.08.2005	03.08.2025	15.06.2018	12.06.2021 page no. 30

Note:- Assisted in technical evaluation in reference to letter no. BMSIC/40025/26-2020/9677 dt 15-03-2021 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.

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