

TENDER NO. BMSIC/DRUGS/20-06

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

Company Name : Voxture Bio Ltd.

Total Number of Pages Submitted in bid documents: 297

Sl. No	SBD clause serial No	Description 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	297	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 :- No. of drugs quoted Upto 5 drugs/Kits:- Rs1,00,000/- (One Lakh only)	Yes	136-138	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	291-295	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.	No	—	No	Not found in the soft 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	51-53	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	82-135	Yes	
7	3.(m)	Copy of Income Tax Return for any three of last four Consecutive Assessment years should be submitted (self-attested).	Yes	139-289	Yes	
8	3.(p)	Copy of PAN Card of the bidder company should be submitted (self-attested).	Yes	296	Yes	
9	3.(q)	Copy of certificate of valid GST registration of the bidder company should be submitted (self-attested).	Yes	80-81	Yes	

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

Company Name:- Voxtur Bio Limited, Plot No. A1, Royal compound, Kaman Bhiwandi Road, Palghar-401208, Maharashtra

Total Number of Pages Submitted in bid documents:- 297

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	Not Submitted
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	51-52	Yes	
3	3.(f)	Minimum three years old valid Manufacturing License of the product quoted with latest license renewal certificate.	Yes	44-45	Yes	
4		Approved product list as per the license issued for quoted product for minimum three years as applicable.	Yes	44-45	Yes	
5		Manufacturing License along with approved product list must be valid till the last date of the submission of tender.	Yes	44-45	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	49	Yes	

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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	
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).	Yes	26-30	Yes	
11		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.	Yes	44-45	Yes	
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 products 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.	Yes	49	Yes	
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 (where ever applicable). It should be not more than one year old. Self-attested copies are to be submitted.	Yes	50	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	54	No	Submitted Certificate not issued from concerned Drug Department

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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	43 (Annexure-VIII)	No	MPCC issued by concerned Department not submitted
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	42	Yes	
18	3.(o)	List of items quoted in prescribed format as per Annexure-III duly signed..	Yes	47	Yes	
19	5.(k)	An Affidavit (with stamp) regarding acceptance of tender conditions to be submitted by the bidding firm as per Annexure-IV.	Yes	53	Yes	
20	5.(l)	Filled check list as per given Annexure-VI to be submitted at the time of uploading the bid.	Yes	21-23	Yes	
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.	NA	NA	NA	
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, where ever applicable. In extraordinary case the Managing Director has discretion to take decision. Explanation- In order to ensure procurement of the tendered products 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."	Yes	24	Yes	
24		Performance statement (For the period of last three year) - Annexure-IX	Yes	25	Yes	

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TENDER NO. BMSIC/DRUGS/20-06

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

Company Name:- Voxtur Bio Limited, Plot No. A1, Royal compound, Kaman Bhiwandi Road, Palghar-401208, Maharashtra
Total Number of Pages Submitted in bid documents:- 297

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	3	HBsAg (Rapid Test)	Rapid Immuno Chromatography lateral flow test for detection of HBsAg in Human Serum/Plasma/Whole Blood)	1. Should be coated with monoclonal antibodies covering all subtypes and variants of HBsAg. 2. The assay should be able to detect surface antigen to Hepatitis B virus. 3. Should be compatible with plasma and serum both. 4. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit. 5. The kit should have approval of the statutory authority from the country of origin. 6. In case of imported kits it should be registered and licensed by the DCG(I) 7. In case of indigenous manufactures should be licensed by the competent authority/ licensing authority defined under Drugs and Cosmetics Act (1940) and medical device rule 2017. 8. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port/place of discharge of consignees. 9. The total procedure time shall not be more than 30 minutes. 10. The assay component should include positive and negative controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls) which may be provided along with the kits if not a part of the kit. 11. The assay should have sensitivity of 100% and specificity of more than or equal to 98% as per the office order of MoHFW vide F. No. 29/Misc./4/2016-DC(65) dated 13/06/2017. 12. The control dot/ band should be able to detect the presence of human immunoglobulin and should not be just a "procedural control" or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology. General Specifications 1. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-80 C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO. 2. The pack size should not be more than 50 tests wherein each test is individually packed. 3. 8 kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and four kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters. 4. The kit will be evaluated on the above parameters by the centers approved by the program. The committee approved the specification of HBsAg (Rapid Test) .	ICMR approval not submitted	Per Test Kits	01,05,10,20,25,30,50,100 Tests	Test Kits	Test Kits	12.10.2015	11.10.2020	Generic	Submitted

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2	4	HBsAg (Rapid Test)- whole blood	Rapid Immuno Chromatography lateral flow test for detection of HBsAg in Human Serum/Plasma/Whole Blood)	1. Should be coated with monoclonal antibodies covering all subtypes and variants of HBsAg. 2. The assay should be able to detect surface antigen to Hepatitis B virus. 3. Should be compatible with whole blood. 4. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit. 5. The kit should have approval of the statutory authority from the country of origin. 6. In case of imported kits it should be registered and licensed by the DCG(I) 7. In case of indigenous manufactures should be licensed by the competent authority/ licensing authority defined under Drugs and Cosmetics Act (1940) and medical device rule 2017. 8. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port/place of discharge of consignees. 9. The total procedure time shall not be more than 30 minutes. 10. The assay component should include positive and negative controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls) which may be provided along with the kits if not a part of the kit. 11. The assay should have sensitivity of 100% and specificity of more than or equal to 98% as per the office order of MoHFW vide F. No. 29/Misc./4/2016-DC (65) dated 13/06/2017. 12. The control dot/ band should be able to detect the presence of human immunoglobulin and should not be just a "procedural control" or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology. General Specifications 1. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-80 C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO. 2. The pack size should not be more than 50 tests wherein each test is individually packed. 3. 8 kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and four kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters. 4. The kit will be evaluated on the above parameters by the centers approved by the program. The committee approved the specification of HBsAg (rapid test) on BIDS-DRUGS AND TESTING KITS TENDER FY 2020-2022 33 whole blood samples.	ICMR approval not submitted	HBsAg test consists of Nitrocellulose membrane coated with antibodies specific to HBsAg and anti rabbit IgG and anti HBsAg and rabbies IgG conjugated to gold particle which is placed between the sample pad (-)	Per Test Kits	01,05,10,20,25,30,5 0,100 Tests	Test Kits	Test Kits	12.10.2015	11.10.2020	Generic	Submitted
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TENDER NO. BMSIC/DRUGS/20-06

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

Company Name:- Voxtur Bio Limited, Plot No. A1, Royal compound, Kaman Bhiwandi Road, Palghar-401208, Maharashtra
Total Number of Pages Submitted in bid documents:- 297

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	3	HBsAg (Rapid Test)	28	MH/101500	NA	NA	12.10.2015	11.10.2020	Not Submitted	Not Submitted
2	4	HBsAg (Rapid Test)- whole blood	28	MH/101500	NA	NA	12.10.2015	11.10.2020	Not Submitted	Not Submitted

Note:- Assisted in technical evaluation in reference to letter no.BMSIC/40015/41-2019/4653 dt 09.09.2020 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 discreprencies are observed for rectification.

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