

Tender Reference no.BMSIC/DRUGS/18-02

S.N.	Technical Eligibility Criteria as per NIT	<p>Firm Name - M/s. MERIL DIAGNOSTICS PVT. LTD. Corporate Address: 601, Midas, Sahar Plaza Complex, J. B. Nagar, Andheri Kurla Road, Andheri (East). Mumbai-400059.Andheri (East). Mumbai-400059. Manufacturer Address:- Survey No. 135/ 139, Bilakhia House, Muktanand Marg, Chala, Vapi – 396191, Tel No: 0260 3052100, Fax No: 0260 3052125</p>										
1	Constitution of the Bidding Company/Firm such as Memorandum of Association and Article of Association with complete address. As per Clause 3(c).	<p>a) Scanned copy of Memorandum of Association dated 07.04.2011 of M/s Meril Diagnostics Pvt. Ltd. is submitted. (Pg. no.-156 to 171) b) Scanned copy of Article of Association dated 07.04.2011 of M/s Meril Diagnostics Pvt. Ltd. is submitted. (Pg. no. 145 to 155) c) Scanned copy of Certificate of Incorporation (Corporate Identity Number- U33110GJ2011PTC 064994 dated 18.04.2011) of M/s Meril Diagnostics Pvt. Ltd. issued by Assistant Registrar of Companies, Gujarat, Dadra and Nagar Haveli is submitted. (Pg. no- 172) d) Scanned copy of bidder information/ bidder details is submitted as per annexure v of NIT. (Pg. no- 197)</p>										
2	Power of Attorney or Resolution of Board by which the authorised signatory has been authorised by bidder firm to sign the documents. As per Clause 3 (e) of the NIT.	<p>a) Scanned copy of Certified True copy of the resolution passed by the board of Directors of the company at their meeting held on 23.11.2015 is submitted wherein it is resolved that Mr. Prakash Tickchandani, Deputy General Manager, Distribution & FFM be and is hereby authorised to sign and submit any bid, quotations, tender issued government, semi government or any other agency from time to time, on behalf of the company. (Pg. no- 142) b) Scanned copy of Power of Attorney is submitted by bidder wherein it is stated that M/s Meril Diagnostics Private Limited hereby appoint and constitute Mr. Prakash Tickchandani, Deputy General Manager, Distribution & Field Force Mgm. sales Administration as its true and lawful attorney to authorised to sign and submit any bid, quotations, tender issued any institutions, company, government, semi government or any other agency from time to time, on behalf of the company. (Pg. no- 143 to 144)</p>										
3	List of item Quoted in prescribed format as Annexure III as per Clause 3 (o)	<p>Scanned copy of list of items quoted is submitted as per Annexure-III of NIT (Total no. of items quoted-01) [pg. no.-141]</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">NIT Sr. no.</th> <th style="text-align: left;">Name</th> <th style="text-align: left;">Specification/Strength</th> <th style="text-align: left;">Dosage Form</th> <th style="text-align: left;">Pack Size</th> </tr> </thead> <tbody> <tr> <td style="vertical-align: top;">2.</td> <td style="vertical-align: top;">Whole Blood finger Prick test for HIV kits.</td> <td style="vertical-align: top;">Attached as Annexure VIII</td> <td style="vertical-align: top;">Kit</td> <td style="vertical-align: top;">--</td> </tr> </tbody> </table> <p>Note:- "As per tender specification" is mentioned in specification column, "NA" is mentioned in Dosage form column and Pack size is mentioned as 50 Test/Kit in submitted list of items quoted.</p>	NIT Sr. no.	Name	Specification/Strength	Dosage Form	Pack Size	2.	Whole Blood finger Prick test for HIV kits.	Attached as Annexure VIII	Kit	--
NIT Sr. no.	Name	Specification/Strength	Dosage Form	Pack Size								
2.	Whole Blood finger Prick test for HIV kits.	Attached as Annexure VIII	Kit	--								

Dhiman 08/05/18
Arun 08/05/18
Lakshmi 08/05/18
Nitya 08-05-18
Sudh 08/05/18
M.K 08/05/18
Ad 09/05/18
Anshu 9/5/18

4	<ul style="list-style-type: none"> • Minimum three years old valid manufacturing licence/Industries Licence/Concerned Government Licence of the product quoted with latest license renewal certificate. As per clause 3(f). • Approved product list as per the license issued for quoted drugs/tender items for minimum three years. As per clause 3(f). • Manufacturing License/Industries licence/Concerned Government Licence along with approved product list must be valid till the last date of the submission of tender. As per clause 3(f). • 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. • 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 Organization). 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 apply. • 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. <ul style="list-style-type: none"> • FFS (Flow Fill & Seal Process) Technology will be accepted wherever applicable. <p>* An Affidavit is to be given for the concerned Clause wherever Non-Drug is mentioned.</p> <p>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. As per Clause 3(f)</p>	<p>a) Scanned copy of License to work a factory (No. 18981 dated 06.01.2016) in Form no. 4 of M/s Meril Diagnostics Pvt. Ltd. Survey No. 135/2/B & 174/2 Bilakhia House, Muktanand Marg Chala, pardi, dist- Valsad, issued by Deputy Director, Industrial Safety and Health Valsad is submitted. (Pg. no-132)</p> <p>b) Scanned copy of Approved Additional product list (No. AP/Meril Diagnostics/2014/28599/B1 dated 26.03.2014) issued by For Commissioner, FDA, Gujarat State is submitted wherein it is stated that M/s Meril Diagnostics Pvt. Ltd. Survey Mp/ 135/2/B, First Floor, Bilakhia House, Muktanand Marg, Chala, Vapi- 396191 is permitted to manufacture & market the Product- <u>One Step Rapid Test for Detection of Anti- HIV in Human Serum Plasma/ Whole Blood with Brand Name MERISCREEN HIV 1-2 WB & without Pack Size.</u> (Pg. no- 140)</p> <p>c) Scanned copy of another approved product list under Form 28 without Signature of, For Commissioner, FDA, Gujarat State Gandhinagar is submitted wherein the above mentioned product is to be manufactured by the firm under License no. G/28/1438 dated 10.04.2013 valid upto 09.04.2018. (Pg. no- 133 to 134)</p> <p>Note- i) Manufacturing Licence in form 28 is not submitted by the bidder.</p> <p>ii) Another approved list (List of Products under Form 28) is not signed by Drug Control Administration.</p> <p>iii) pack size is mentioned as 40 Test/ 30 Test/ 10 Test in this approved list, but bidder has submitted 50 Test in Pack size column in Annexure III (List of quoted items).</p> <p>d) Scanned copy of Market Standing Certificate (Mfg/ Market Standing Certificate/2017/Sc-1/44296/B1 dated 25.04.2017) issued by For Commissioner, FDA, Gandhinagar is submitted wherein it is stated that the firm is manufacturing for sale following product since last three financial years 2014-15, 2015-16 and 2016-17. (Pg. no- 129 to 130)</p>
5	<p>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. As per Clause 3(g)</p>	<p>NA</p>
6	<p>Self attested copies of Market standing certificate (in India) of minimum three years, issued by the concerned Licensing Authority from Drugs Control Department for the quoted product. As per Clause 3(h)</p>	<p>NA</p>
7	<p>Self attested copy of Non Conviction Certificate (NCC), issued by the concerned Licensing Authority from Drug Control Administration of the state for last three years. It should be not more than one year old. As per Clause 3(i).</p>	<p>Scanned copy of Non-Conviction Certificate (No. Certi/Meril Diag./2017/109719/ B1 dated 04.10.2017) issued by For Commissioner, FDA, Gujarat State, Gandhinagar is submitted wherein it is stated that M/s Meril Diagnostics Pvt. Ltd. is so far not convicted in Gujarat State for the contravention of Drugs & Cosmetics Act 1940 & Rules thereunder. (Pg. no-127 to 128)</p>
8	<p>Self attested copies of WHO-GMP/GMP as per revised Schedule- 'M'/COPP Certificate of the manufacturing unit issued by the Licensing Authority / Concerned Govt. Department/ BIS/ ISI Certificate issued from Concerned Department. The GMP certificate must not be older than one year form the last date of submission of tender. As per clause 3(j).</p>	<p>Scanned copy of Certificate (No. 1712500 dated 11.12.2017) issued by Commissioner, FDA, Gujarat State, Gandhinagar is submitted wherein it is stated that M/s Meril Diagnostics Pvt. Ltd. M/s Meril Diagnostics Pvt. Ltd. complies with Good Manufacturing Practices for the dosage forms, catories and activities listed below. This certificate remains valid until 10.12.2019 (Pg. no-125 to 126)</p>

Amal 08/05/18
Pravin 08/05/18
Amal 08/05/18
Lokesh 08/05/18
Harsh 08-05-18
Pratik 08/05/18
Pratik 09/05/18
Archana 09/05/18

9	Self attested copies of Maximum Production Capacity Certificate (section wise) issued by concerned Licensing Authority from Drugs Control Department/Concerned Govt.department highlighting the quoted product section.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. Importers will have also to submit Invoices/Evidence of import in items of said product with quantity details. As per Clause 3(k).	Scanned copy of production capacity certificate (No. Mfg/Production capacity certificate/2017/Sc-1/11928/B1 dated 04.02.2017) issued by For Commissioner, FDA, Gandhinagar, Gujarat State is submitted wherein Annual Production Capacity (Triple Shift) of Department Name- Rapid Diagnostics Test is mentioned as 1125000 kits/year (45000000 Tests/year) (Pg. no. 123 to 124)			
10	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 last date of submission of the tender) by Central Government/ Central Government Agencies/any state government/any of the state government agencies/any Drug Procurement Agencies or by BMSICL as per Annexure II (clause 3(n) of NIT).	Scanned copy of notarised affidavit (with Stamp) for Non Blacklisting is submitted as per annexure-II of NIT (Pg no-118)			
11	EMD details (DD number/BG number and date with issuing bank) as per Clause 3(b) .	RBL BANK	D.D no:-"141476"	Rs.1,00,000/-	Pgno:-117
12	Tender Fee Rs 10,000/- in form of DD as per Clause 3(a).	RBL BANK	D.D no:-"141477"	Rs.10,000/-	Pgno:-116
13	Self attested copies of the Audited Annual Balance Sheet and Profit and Loss statement showing details of their annual average turnover not less than 5 crores for any three of the last four consecutive financial years. (Auditor/ C.A. Certificate of turnover will not be accepted).Self attested copies are to be submitted. As per Clause 3(l)	F.Y.-2013-2014	Rs.7.31 (in crore)	Pgno:-110	
		F.Y.-2014-2015	Rs.28.10(in crore)	Pgno:-110	
		F.Y.-2015-2016	Rs.36.75(in crore)	Pgno:-76	
14	Self attested copy of Income Tax Return for any three of last four consecutive Assessment years. As per Clause 3(m).	F.Y.-2014-2015		Pgno:-07	
		F.Y.-2015-2016		Pgno:- 06	
		F.Y.-2016-2017		Pgno:-05	
15	Self attested copy of PAN Card of the Bidder Company. As per Clause 3(p)	PAN no:-"AAHCM1404G"		Pgno:-04	
16	Copy of certificate of valid GST registration of the bidder company should be submitted (self-attested). As per Clause 3(q)	Submitted		Pg no:-03	
17	Affidavit (with stamp)declaration regarding acceptance of tender conditions to be submitted by the bidding firm as per Annexure IV (Clause 5(k) of NIT).	Scanned copy of notarised affidavit (with Stamp) regarding Acceptance of Tender Conditions is submitted as per annexure IV of NIT (Pg. no-1 to 2)			
<p>The facts in clause No-1 to 10 and 17 of the provided sheet has been compiled with due diligence and care, on the basis of document provided by BMSICL, inspite, some inadvertent discrepancies could have been crept in. Humble request to all concerned to bring to notice in due time if any discrepancies are observed for rectification.</p> <p>Opinion of Concerned authority should be taken as the quoted products comes under Medical Device.</p>					

Devi
08/05/18

Amr
08/05/18

Sanjay
08/05/18

Mane
08.05.18

P.K
08/05/18

Ad
09/05/18

Ankush
9/5/2018