

Tender Reference no.-BMSIC/DRUG/17-11

Technical Eligibility Criteria as per NIT

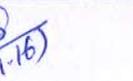
Firm Name - Transasia Bio-Medicals Ltd.

Corporate Address:- Transasia House 8 Chandivali Studio Road, Andheri (East) Mumbai-400072

Manufacturer Address:-Transasia Bio-Medicals Ltd., A-B /11, O.J.D.C Ringanwada , Daman-396210

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) Self attested Scan copy of Certificate of incorporation No. 11-36198 dated 10/05/1985 for Transasia Bio-medicals Private Ltd. submitted (Page No.15 & 127)</p> <p>(b) Self attested Scan copy of certificate of change of name from Transasia Bio-medicals Private Ltd. to Transasia Bio-medicals Ltd. submitted. Issue date 13/11/1994 (Page No.16 & 128)</p> <p>(c) Self Attested Memorandum of association along with Director Name and Address submitted. (Page No. 11-14 & 122-126)</p> <p>(d) Self attested First page of Memorandum and Article of association Submitted (Page No. 17 & 129)</p> <p>(e) Article of Association is not submitted .</p> <p>(f) Bidder information details as per Nit Annexure-V submitted (page No. 94)</p> <p>(g) Self attested copy of subscriber detail attached by which it is clear that Mr. Suresh Hassanand Vazirani and Prakash Hassanand Vazirani are the subscriber. (pg. no.-12)</p> <p>Note:- 1)Minimum seven subscriber required for public ltd. company. 2)Subscriber detail attached with AOA & MOA is of year 1985 whereas the fresh certificate of incorporation is of year 1994.</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.	Self attested copy of specific power of attorney is attached by which Suresh Vazirani, Chairman & Managing Director of Transasia Biomedicals Ltd. Has constitute, appoint and authorized Mr. Ghanshyam are Ganatra (Manager Sales Administration) to be true and lawful attorney of the company is signed tender documents. (pg. no.-120-120)										
3	List of item Quoted in prescribed format as Annexure III as per Clause 3 (o)	<p>Self attested Scanned copy of Annexure -III is submitted with heading i.e. "List of quoted items". (Page No.4 & 119)</p> <p>No. of quoted item/s - 1</p> <table border="1"> <thead> <tr> <th>NIT Sl. No.</th> <th>Name of Drug</th> <th>Specification</th> <th>Packsizes</th> <th>Dosage form</th> </tr> </thead> <tbody> <tr> <td>12</td> <td>Dengue NS1 Antigen Kit (ELISA Based)</td> <td>Erba Lisa Dengue NS1 Ag ELISA Kit</td> <td>96 test</td> <td>N/A</td> </tr> </tbody> </table>	NIT Sl. No.	Name of Drug	Specification	Packsizes	Dosage form	12	Dengue NS1 Antigen Kit (ELISA Based)	Erba Lisa Dengue NS1 Ag ELISA Kit	96 test	N/A
NIT Sl. No.	Name of Drug	Specification	Packsizes	Dosage form								
12	Dengue NS1 Antigen Kit (ELISA Based)	Erba Lisa Dengue NS1 Ag ELISA Kit	96 test	N/A								

4	<ul style="list-style-type: none"> • Minimum three years old valid manufacturing 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 for minimum three years. As per clause 3(f). • Manufacturing License 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. • 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. • FFS (Flow Fill & Seal Process) Technology will be accepted wherever applicable. <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) Self Attested Scanned copy of Renewal of Licence to manufacture on form 26 bearing Licence No. DD/314 & DD/315 Originally Granted on 27/03/2002 submitted. further it is stated that the licence will be in force from 27/03/2017 to 26/03/2022. (Page NO. 20 & 117)</p> <p>(b) Original copy of Licence No. DD/314 & DD/315 is not Submitted</p> <p>(c) Self attested Scanned copy of approved product list is submitted ,issued by Drugs Licencing Authority,Drugs Control Department,U.T. of Daman & Diu,Daman valid from 27/03/2002 to 26/03/2017 (page 19 & 116). Renewal copy of product approval Not Submitted.</p> <p>(d) Self attested Scan copy of Maket standing certificate No. DCD/D&D/LA/2016-2017/618 dated 14/07/2016 issued by Drug Licencing authority, Drug control department, U.T. of Daman & Diu,Daman, submitted. Certificate is issued to participate in va rious Govt. tender. (Page No. 18 & 113)</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>N/A</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>Self attested Scan copy of Maket standing certificate No. DCD/D&D/LA/2016-2017/618 dated 14/07/2016 issued by Drug Licencing authority, Drug control department, U.T. of Daman & Diu, Daman, submitted. Certificate is issued to participate in various Govt. tender but in list of product Erba Lisa Dengue NS1 Ag ELISA Kit is missing. (Page No. 18 & 113)</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>Self Attested Scan copy of Non Conviction certificate, No. DCD/D & D/LA/2017-18/771, issued by Dr. Dharmesh Agrawal,Drugs Licensing Authority, UT of Daman & Diu dated 19/08/2017, submitted but Validity date not mentioned in the certificate. (Pg. - 9 & 112)</p> <p>Note:- In list of product Erba Lisa Dengue NS1 Ag ELISA Kit is missing.</p>

one more        

8	Self attested copies of WHO-GMP/GMP 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 form the last date of submission of tender. As per clause 3(j).	1. Self attested Schedule M- GMP certificate No. DCD/D&D/LA/2016-2017/742 dt. 08/08/2016 submitted. This certificate is Valid for 1 Year from the date of Issue. (Page No. 26-27 & 109-110) 2. Self attested Letter Ref No. TBM/DRM/FDA/2017/23 dt. 04/09/2017 for renewal of Schedule M-GMP certificate (Revised Schedule-M) Duly accepted by Drugs Control Department submitted. (Page No. 28 & 111) 3. Self attested Certificate of Registration Certificate No. 11450199.PDSX of Transasia Bio-Medicals Ltd. Valid from 18/02/2017 to 15/09/2018 Submitted Self attested Notarised Certificate of ISO 9001:2008 (No. 11450199.PDSX) Submitted Valid from 18/02/2017 to 15/09/2018 (Page No. 89- 90) 4. Self attested Certificate of Registration Certificate No. 11450199.PDWS of Transasia Bio-Medicals Ltd. Valid from 18/02/2017 to 28/09/2019 Submitted Self attested Notarised Certificate of ISO 13485:2003/ Cor 1:2009 EN ISO 13485:2012 (No. 11450199.PDWS) Submitted Valid from 18/02/2017 to 28/09/2019 (Page No. 87-88)
9	Self attested copies of Maximum Production Capacity Certificate (section wise) issued by concerned Licensing Authority form Drugs Control 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 Request letter, Ref. No.DRM/FDA/2017/29, submitted to Drugs control Department, P.H.C. Daman (duly received by Clerk dt. 18/10/2017) for Maximum production capacity Certification dated 18/10/2017 submitted. Production capacity Certificate not submitted. (Page No. - 5)
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).	Self attested Notarised Scan copy of Non-Blacklisting affidavit on Rs.100/- Non-Judicial stamp paper submitted as per annexure-II of NIT by Authorised person of Transasia Bio-Medicals Limited. (Page No.-10 & 107)
11	EMD details (DD number/BG number and date with issuing bank) as per Clause 3(b) .	Bank Guarantee bearing No. 240GT02172900014 dt.17/10/2017 for EMD of Rs.100000/- of HDFC bank submitted (Page No. 31-34 & 133-136)
12	Tender Fee Rs 10,000/- in form of DD as per Clause 3(a).	DD NO. -"613724" of HDFC bank dt. 16/10/2017 Rs.10,000/- Page No-1 & 132
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 25 crores for any three of the last four consecutive financial years. (Auditor/ C.A. Certificate of turnover will not be accepted). As per Clause 3(l)	Financial Year :-2013-14 Rs.472.59 (in crore) pg no:-38 Finnacial Year -2014-15 Rs.529.56(in crore) pgno:-40 Financial Year- 2015-16 Rs.604.14(in crore) pgno:-40
14	Self attested copy of Income Tax Return for any three of last four consecutive Assessment years. As per Clause 3(m).	AY-2014-15 Page No-22 & 99 AY-2015-16 Page No-23 & 100 AY-2016-17 Page No-24 & 101
15	Self attested copy of PAN Card of the Bidder Company. As per Clause 3(p)	PAN No- AAAC2038C Page No- 8 & 98
16	Self attested copy of Certificate of valid Sales tax/VAT registration of the bidder company. As per Clause 3(q)	GST Registration No -"10AAACT2038C1Z8" Page No-25 & 97
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).	Notarised Specific power of Attorey in favour of Mr. Ghanshyam R. Ganatra, Manager-Sales Administration, duly Authorised by Mr. Suresh Vazirani,Chairman and Managing Director of Transasia Bio-Medicals Limited on Rs. 500/- Non Judicial Stamp Paper submitted. (Page No. 2-3 & 95-96)

The facts in clause No-1 to 10 and 17 of the provided sheet has been compiled with due deligence and care, on the basis of document provided by BMSICL, in compliance of letter No 1146(15) Dt-05.11.2016 of Health Department, Govt of Bihar . Inspite, some inadvertent discrepencies could have been crept in. Humble request to all concerned to bring to notice in due time if any discrepencies is observed for rectification.

one have  Kanichi  Arun,    (11-16)