Tender Reference no.-BMSIC/DRUG/16-07

S.N.	Technical Eligibility Criteria as per NIT	Firm Name - Bharat Serum & Vaccines Ltd. Corporate Address: 3rd floor, Liberty tower, Plot no.-K-10, Kalwal Industries Estate, Ariole, Navi Mumbai- 400708 Manufacturing Unit Address:Plot no-K-10,Additional MIDC,Anandnagar Ambarnath East Distric, Thane-421501
1	Constitution of the Bidding Company/Firm such as Memorandum of Association and Article of Association with complete address. As per Clause 3(c).	(a) Photo copy of memorandum of association of Bharat Serum and vaccines ltd. is submiteed. [Pg. no.-71 to 76] (b) Self attested copy of memorandum of association of Bharat Serum and vaccines ltd. is also submiteed. [Pg. no.-211 to 216] (c) Self attested articles of association of Bharat Serum and vaccined ltd. is submiteed. [Pg. no.-77 to 190] (d) Self attested copy of certificate of incorporation no-15134 of 1971-72 issued by Addl. Registrar of companies, Maharastra on 29th April 1971 of M/s Gautam Laboratories Pvt. ltd. is submitted. [Pg. no.-218] (e) Self attested copy of fresh certificate of incorporation (No.15134/CTA dated 14-03-1983) consequence on change of name is also submitted where in it is stated that **the name Gautam Laboratories Pvt. Ltd**. having dully passed the necessary resolution in terms of section 21 of the companies act, 1956 and the approval of the central Government, **the name of the said company is this day changed to Bharat Serums & Vaccines ltd**. [Pg. no.-217] (f) Photo copy of Bidder information/Bidder details as per Annexure V of NIT along with list of directors is submitted. [Pg. no.-69 to 70]
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 Power of attorney dated 14 Feb. 2014 is submitted where in it is stated that Bharat Serums and Vaccines ltd, do hereby nominate, constitutem, authorise and appoint **Mr. Adeet Ghosh, Group vice president, to be the true and lawful attroney**. [Pg. no.-299 to 301]
3	List of item Quoted in prescribed format as Annexure III as per Clause 3 (o)	Self attested copy of list of items quoted is submitted as Annexure-III of NIT. [Pg. no-305 to 306] No. of items quoted-08 (Eight) **S. no. / NIT S. No. / Name of Drug / Specification** 1. 86 Anti D (Rho) Immunoglobulin 150 µg vial (Intramuscular Injection) 2. 87 Anti D (Rho) Immunoglobulin 300 µg vial (Intramuscular Injection) 3. 88 Tetanus Immunoglobulin IP 250 IU vial Injection 4. 89 Tetanus Immunoglobulin IP 1000 IU vial Injection (Note:- The specification in list of item quoted is mentioned as 500 IU) 5. 97 Rabies Immunoglobulin (Human inj.) (IP, BP, USP,EUPh, Official compendium) 150IU/ml 6. 99 Streptokinase injection IP 7.5 lakh units vial Injection (Note:- NIT sl. no. in list of item quoted is mentioned as 98) 7. 98 Rabies AntiSerum IP 300 IU/ml 5ml vial (Note:- the specification & NIT sl. no. in list of item quoted is mentioned as 300IU/5ml and 99 respectively) 8. 107 Anti Snake Venom Serum 10 ml (Lyophilized) 10 ml vial

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4	• 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. 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)	Self attested copy of <u>licence to manufacture for sale or distribution</u> of large volume parenterals/Sera and vaccine in <u>Form 28 D [Licence No.-KD/4 date of issue 27-06-2003]</u> issued by licensing Authority, Joint commissioner (Konkan Division) FDA (M.S.) thane and central licence approving authority, New Delhi **along with a attached list of items to be manufactured is submitted**. wherein it is stated that the **licence shall be in force from 27-06-2003 to 26-06-2008.** The quoted items mentioned at NIT S. No. 98 and 107 is mentioned at S. No. 1 and 3 of the attached list. [Pg. no.274 to 275] *** Note:- The name of drug at NIT Sl.no. 107 is mentioned as Snake Venom Antiserum IP (Lyophilized) at sl.no.-1 of the attached list of product.** (b) Self attested copy of **certificate of renewal of licence no. KD-4** granted on 27-06-2003 along with list of items attached is submitted in Form 26-H where in it is stated that the licence has been renewed from 27/06/2008 to 26/06/2013. The list of items quoted at NIT S. No. 98 and 107 is mentioned at S. no. 1,3 and 4 of the attached list. [Pg. no.-270 to 273] (c) Self attested copy of certificate of renewal in Form 26 H along with list attached issued on 03-10-2013 is submittd where in it is stated that **licence No. KD-4 granted on 27-06-2003 has been renewed from 27-06-2013 to 26-06-2018.** The quoted items mentioned at NIT S. No. 98 and 107 is mentioned at S. No.1, 2 and 24 of the said attached list. [Pg. no-266 to 269] (d) Self attested copy of **licence to manufacture and store** blood products for sale or distribution **[licence No-KD-5 date of issued 01-07-2004]** along with list of product is submitted where in it is stated that the **licence shall be in force from 01-07-2004 to 30-06-2009.** **Note:- The quoted items mentioned at NIT S. No. 88 & 89 with specification I.P are mentioned at S. No.7, 10 and 9,12 respectively with specification B.P of the said attched product list. [Pg. no.-286 to 288]** (e) Self attested copy of certificate of renewal in Form 26-I along with approved product list is submitted where in it is stated that **licence No. K.D-5 granted on 01-07-2004 is hereby renewed with effct from 01-07-2009 to 30-06-2014.** The quoted items mentioned at NIT S. No. 88 and 89 are mentioned at S. No.7, 10 and 9, 12 respectively of the said attached list. [Pg. no/-281 to 283] **Note:-** 1) The specification of drugs mentioned at NIT sl.no. 88 & 89 in attached approved product list has changed from B.P to I.P with effect from 01-01-2012. 2) The specification of drug mentioned at NIT Sl. no.- 86 & 87 has been struck off on 01/10/2010 in approved product list. 3) The specification (reference of official compendium) of drugs mentioned at NIT sl.no. 86 and 87 is not mentioned in NIT. (h) Self attested copy of **certificate of Renewal issued** on 16/07/2014 along with list of product is submitted wherein it is stated that **licence No. KD/5 granted on** 01/07/2004 is hereby **renewed with effect from 01/07/2014 to 30/06/2019.** The quoted items mentioned at NIT S. No. 86,87,88 and 89 are mentioned at (23,26), (21,24,25), 10 and 12 respectively of the said attached approved product list. [Pg. no.-276 to 280] at S. No. 23-Anti-D (Rho) Immunoglobulin (Monoclonal) 150 mcg at S. No.-26-Anti-D (Rho) Immunoglobulin (Monoclonal) 150 mcg (Freezed dried) at S. No.-21-Anti-D (Rho) Immunoglobulin (Monoclonal) (Freeze Dried)300 mcg at S. No.-24-Anti-D (Rho) Immunoglobulin (MonoclonalLiquid Injection) (Monoclonal) 300 mcg at S. No.-25-Anti-D (Rho) Immunoglobulin Injection (Freeze Dried) (Monoclonal) 300 mcg (i) Self attested copy of licence to manufacture for sale [or for distribution of] drugs in form 28 [Licence No.-KD-360 date 07/09/2002] along with approved product list attached is submitted wherein it is stated that the licence shall be in force from 07/09/2002 to 06/09/2007. [Pg.no.- 296-298] The quoted items mentioned at NIT S. No. 99 is mentioned at S. No. 1 and 3 of the said attached list. (j) Self attested copy of certificate of Renewal of licence in form 26 along withapproved product list issued on 08-01-2008 is submitted wherein it is satated that licence 28/KD-360 granted on 07/09/2002 has been renewed from 07/09/2007 to 06/09/2012. [Pg. no.-293 to 295] The quoted items mentioned at NIT S. No. 99 is mentioned at S. No. 1 of the said attached list. (k) Self attested copy of certificate of Renewal in form 26 along with product list issued on 18-01-2013 is submitted wherein it is satated that licence 28/KD-360 granted on 07/09/2002 has been renewed from 07/09/2012 to 06/09/2017. [Pg. no.-289 to 292] The list of items quoted at NIT S. No. 99 is mentioned at S. No. 02 and 103 of the said attached list. (l) Self attested copy of Licence to sell, stock or exhibit (or offer) for sale or distribution by wholesale in Form 20B and 21 B (validity-03-12-2013 to 02-12-2018) is submitted. [Pg. no.40- to 41] (m) Self attested copy of Manufacturing & Marketion certificate [No.-6071039 dated 11/08/2016] issued by Licensing Authority, FDA, Konkan Division, Maharastra state is submitted wherein it is state that Bharat Serums & vaccines Ltd. is permittd to manufacture following products as mentioned below and the above products are being marketed by the firm since last 3yrs. This certificate is valid for a period 11/08/2016 - 10/08/2017. The list of items quoted at NIT S. No. 98,99,87,86,107 and 88 are mentioned at S. No. 1,2,3,4,5 and 6 respectively. [Pg. no.-204-205] (n) Self attested copy of Manufacturing & Marketion certificate [No.-6063082 dated 24/02/2015] issued by Licensing Authority, FDA, Konkan Division, Maharastra state is submitted wherein it is state that Bharat Serums & vaccines Ltd. is permittd to manufacture following products as mentioned below and the above products are being marketed by the firm since last 3yrs. This certificate is valid for a period 24/02/2015 - 23/02/2016. The list of items quoted at NIT S. No. 98,99,107,89 and 88 are mentioned at S. No. 1,6,7,8 and 9 respectively. [Pg. no.-206-207] (o) Self attested copy of Manufacturing & Marketion certificate [No.-6068356 dated 04/03/2016] issued by Licensing Authority, FDA, Konkan Division, Maharastra state is submitted wherein it is state that Bharat Serums & vaccines Ltd. is permittd to manufacture following products as mentioned below and the above products are being marketed by the firm since last 3yrs. This certificate is valid for a period 04/03/2016 - 03/03/2017. The list of items quoted at NIT S. No. 99,87,98,107 and 88 are mentioned at S. No. 1,3,9,10 and 11 respectively. [Pg. no.-208-209]

5	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)	(a) Self attested copy of **Licence to import drugs (Licence BP-24-62)** in **Form-10** is submitted **(Validity 25 Nov 2011 to 30-06-2014)** **Note:- Specification/Strength -150 IU/ml is not mentioned in approved product list.** [Pg. no.-203] **Note-Rabies Immunoglobulin (Human) Injection at S. No. 97 of NIT is mentioned as Human Rabies Immunoglobulin (Berirab P) solution for IM injection at S. No. 2 (a) of Form 10.** (b) Self attested copy of **Licence to import drugs (Licence BP-24-140) in Form-10** is submitted **(Validity 07 Nov 2014 to 30-06-2017)**. **Note-Rabies Immunoglobulin (Human) Injection at S. No. 97 of NIT is mentioned as Rabies Immunoglobulin (Berirab P) solution for IM 2.0 ml at S. No. 2 (5) of the approved product list.** [Pg. no.-198] **Note:- Specification/Strength -150 IU/ml is not mentioned in Form 10.** (c) Inv. No.-3041915 date 14/09/2012 (page 38) Inv. No. 3030000222 date 06/08/2013 (page36) Inv. No.-3030000066 date 16/03/2015 (page 33) Inv. No.-3030001235 date 25/12/2016 (page30) Inv. No-3030001213 date 20/12/2015 (page 29) **Note:- Invoice showing that the quoted product at NIT Sl. no.- 97 is imported and sold in India for last three years submitted.**
6	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)	(i) Self attested copy of Manufacturing & Marketion certificate [No.-6063082 dated 24/02/2015] issued by Licensing Authority, FDA, Konkan Division, Maharastra state is submitted wherein it is state that Bharat Serums & vaccines Ltd. is permittd to manufacture following products as mentioned below and the above products are being marketed by the firm since last 3yrs. This certificate is valid for a period 24/02/2015 - 23/02/2016. The list of items quoted at NIT S. No. 98,99,107,89 and 88 are mentioned at S. No. 1,6,7,8 and 9 respectively. [Pg. no.-206-207] (ii) Self attested copy of Manufacturing & Marketion certificate [No.-6068356 dated 04/03/2016] issued by Licensing Authority, FDA, Konkan Division, Maharastra state is submitted wherein it is state that Bharat Serums & vaccines Ltd. is permittd to manufacture following products as mentioned below and the above products are being marketed by the firm since last 3yrs. This certificate is valid for a period 04/03/2016 - 03/03/2017. The list of items quoted at NIT S. No. 99,87,98,107 and 88 are mentioned at S. No. 1,3,9,10 and 11 respectively. [Pg. no.-208-209]
7	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).	(a) Self attestd copy of Non conviction certificate (no. 6069815) for manufacturing licence 28-KD/4, 28E-KD/5 & 28-KD/360) valid upto 24-05-2017 is submitted. (pg. no. 241)
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).	(a) self attested **copy of GMP certificate no. 6069838** valid upto date -25-05-2017 for Mfg. licence 28-KD/04,28E-KD/05 & 28-KD/360 is submitted. (pg. no. - 60) (b) Self attested copy of **GMP compliance certificate** of a manufacture (CSL behring Gmblt Germany) issued on 14-10-2014 is submitted. (page. no. - 61 to 65) (c) Self attested copy of **certificate of good manufacturing practices** issued on 28-07-2016 is submitted wherein it is stated that this certificate remains **valid until 26 jul. 2018**. (Page no. 234 to 240)

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).	(a) Self attested copy of capacity and quality certification (section wise) issued on 05-07-2016 by licensing authority , FDA, Konkan division Mahrastra state is submitted. (pg. no. - 242-253) (b) A notarised affidavit (with stamp) regarding the batch production (importing) capacity is submitted for NIT S.NO. 97 (pg. no. - 67) (c) Self attested copy of preformance certificate (no. 6068355 valid upto 03-03-2017) is submitted. (pg. no. - 42 to 43)
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).	A notarised affidavit (with stamp) for non blacklisting is submitted as per Annexure- II of NIT. (Pg. no. - 231 & 233)
11	EMD details (DD number/BG number and date with issuing bank) as per Clause 3(b) .	DD No. " 001535" (IDBI) Dated 04-08-2016 `2,00,000/- Page No.-265
12	Tender Fee Rs 10,000/- in form of DD as per Clause 3(a).	DD No. " 001534"(IDBI) Dated 04-08-2016 `10,000/- Page No:-263

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)	FY-2015-16 `56036.32(Lacs) FY-2014-15 `49316.24(Lacs) FY-2013-14 `36439.58(Lacs) **Note:-Revenue from operation (Net) taken as "turnover"**	Page No :-255 Page No :-257 Page No- 259
14	Self attested copy of Income Tax Return for any three of last four consecutive Assessment years. As per Clause 3(m).	FY-2015-16 FY-2014-15 FY-2013-14	Page No :-310 Page No:-311 Page No:-312
15	Self attested copy of PAN Card of the Bidder Company. As per Clause 3(p)	PAN NO:- "AAACB2431"	Page No:-307
16	Self attested copy of Certificate of valid Sales tax/VAT registration of the bidder company. As per Clause 3(q)	VAT Reg No:-(TIN)27160000248V	Page No:-313
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).	A notarised affidavit (with stamp) regarding acceptance of tender conditions is submitted as per Annexure-IV of NIT. (pg. no. - 308)	

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.