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

S.N.	*Technical Eligibility Criteria as per NIT*	*Firm Name - M/s Biological E. Ltd.* *Corporate Address: 18/1 & 3, Azamabad, Hyderabad-500020* *Manufacturing Unit Address:-18/1 & 3, Azamabad, Hyderabad-500020*
1	Constitution of the Bidding Company/Firm such as Memorandum of Association and Article of Association with complete address. As per Clause 3(c).	Self attested copy of fresh certificate of incorporation consequent on change of name of Biological Evans Ltd Hyderabad to Biological E. Limited along with list of present director in the board of company is submitted (pg no.60 to 62) **Note:** a) In fresh certificate of incorporation consequent on change of name(pg no.60) it is stated that "Regional director company law board,Madrass letter no.4/21/A-3/79 dated 06.09.1979 the name of said company is this day changed to Biological E Ltd and this certificate is issued persuant to section 23(1) of the said act. b) Certificate of in corporation [Pg. no.-61] is not completly legible. (ii) Self attested copy of bidder information/Bidder details signed by Sultan Amir Baig, Assoc vice president finance dated 25-08-2016 as per Annexure-V of NIT is submitted in which S. No. 6 is not filled and written that "Enclosed separately". [Pg. no.-26] **Note:- (1) Coloumn of Sl. No. 6 of bidder information/details is not properly filled rather separate list of directors enclosed. [Pg. no.-62]**
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.	2(a) Self attested copy of authorisation to submit the tender signed by Sree Shaattur Sr. vice president Fin and Account for Biological E. Ltd. **without date** is submitted wherein it is stated that **Mr. Sultan Amir Baig.** Employee of this organisation as associate vice president -**finance is hereby authorised to sign and submit the tender online** vide tender reference no.- REF. No.- BMSIC/Drugs/16-07 dated-20/07/2016 on behalf of this organisation. [Pg. no.-45] (b) Self attested copy of certified true copy the resolution passed at the meeting of the directors of Biological. E. Ltd. held on monday the 14th July 2014 signed by Mahima Datia, Managing Director, Biological E. Ltd. dated14.07.2014 is submitted wherein it is stated that "Resolved that in suppression of all earlier resolutions the following officials of the company be and are hereby several authorised to make offer for sale to sign correspondence and tenders for and on behalf of the company", where in the name of **authorised signatory Mr. Sultan Amir Baig. associate vice president finance is mentioned at S. No.-3.** [Pg. no.-44] (c) **Signature of authorised person on submitted documents does not match with specimen signature as depicted in authroisation certificate. [page no.-45]** (d)**List of present directors in the board of the company submitted without signature and date** (page62) **(II) Memorandum of association and article of assciation not submitted.**
3	List of item Quoted in prescribed format as Annexure III as per Clause 3 (o)	(a) Self attested copy of list of items quoted as per Annex-III dated 25/08/2016 is submitted. [Pg. no.-65] No of items quoted 1 (one) NIT S. NO.-82specification/strength of tetnus toxoid in NIT is mentioned as 0.5 ml where as in submitted list of items quoted specification is mentioned as each dose of 0.5 ml Tetnus Toxoid > 5Lf to <25 Lf (adsorbed on aluminium Phosphate , 1.5 mg) Preservative Thiomersal I.P. -0.01% W/V. **Note: NIT S.no. is blank and 82 is written in column s.no which is not accordance with Annexure-iii of NIT**

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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 Photo copy of Fowarding letter No.-6759/M3A/98 date -30-12-98 issued by director Drug control adminstration govt. of Andhra Pradesh along with licence to manufacture for sale or for distribution of large volume parentral Sera and vaccine in form-28 D bearing licence no.-02/HD/AP/98/V/G inforce from 11-12-1998 (hand written without initial) to 31-12-1999 of M/s Biological E. Ltd. Azamabad, Hyderabad signed dated 22-07-1998 by Director is submitted wherein it is stated that t[illegible]ense shall be inforce from date 11-12-1998 to 31-12-1999. [Pg. no.-47 & 48] (b) Self attested photo copy of Forwarding letter no.- L Dis no.-13447/M3B/2011 dt- 24-01-2014 regarding certificate of renewal of license in form -26 H issued by Director Drugs Control administration Govt. of Andhra Pradesh, Hyderabad dated 06-12-2013 is submitted wherein it is stated that Drug licence no.-02/HD/AP/98/V/R granted on 11-12-1998 to M/s Biological E. ltd. for manufacture of vaccines situated at Azamabad, Hyderabad, Andhra Pradesh has been renewed from 01-01-2012 to 31-12-2016 and approval of additional two products (two only) in form 28-D duly approved by the central licensing approving authority new Delhi vide his letter no.-3rd sited. [Pg. no.-53-54] (c) Self attested photo copy of list of products approved in form -28 D to M/s Biological E. Ltd. issued by Drug controller general, (india) Date General of Health services, FDA Bhawan, Kolkata Road, ITO, New Delhi under Drug license no.-02/HD/AP/98/V/R Dt-11-12-98, renewed from-01-01-2012 to 31-12-2016 and RC no.-13447/M3B/2011 dated-15-01-2014 is submitted.(pg no.52) Wherein Tetnus vaccine (absorbed) I.P. 0.5 ,ml Ampoule, 5 ml vial & 10 ml vial Each ml dose of 0.5 ml contains Tetnus Toxoid ≥ 5L.F to ≤ 25 Lf Adsorbed on Aluminium Phosphate (Alpo 4)≥ 1.5 mg Preservative:- Thiomersal I.P- 0.01% W/V (for domestic) is mentioned at S. no. 01 of said list. [Pg. no.-55 to 59] **Note: Product quoted not highlighted in the approved list as per NIT** (d)Self attested copy of market standing certificate DI/BPN/sEC(mFG)/MSC/29.01.2016-01 dt 05.02.2016 is submitted wherein it is stated that they are manufacturing & marketing the following products for last 3yrs and the quoted product is mentioned at s.no.-1 of the said certificate.(page 33-34) **Note: The above certificate is issued for the purpose of submitting the same to Rajasthan Medical services corporation ltd-Jaipur and other Govt.Agencies in connection with Tender.** **Note:- The licence no. in licence to manufacture is mentioned as 02/HD/AP/98/V/G whereas licence no. in its renewal certificate is mentioned as 02/HD/AP/98/V/R.**

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)	N/A (page no.32)
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)	N/A
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).	Self attested photo copy of non conviction certificate issued vide DI/BPN/Sec(mfg.)/NCC, Msc. & PC/20-07-2016 -02 date 26-07-2016 by Dy director -Hyderabad region (FAC) & issuing authrity Drugs control administration, Govt. of Telangana is submitted wherein it is stated that this is to certify that M/s Biological E. Ltd. situated at 18/1 & 3 Azamabad, Hyderabad-500020 Telangana, India is holding Drug licence bearing no.-02/HP/AP/98/V/R, dated 11-12-1998 in form 28 D (Removed in 26 H) valid upto 31-12-2016 granted and issued by this department under the provision & Drugs and cosmetic act-1940 and Rules under. The said firm has not been convicted for violation of provisions of the said act for the products approved to them for the proceeding three years and no case/proceedings is pending against the firm in any court of law. (Pg. no.-36)

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 photo copy of GMP certificate on letter head of DCA, Drug control administration, Govt. of Telengana issued vide (DIS- 16102/E(v)/TS/2015 dated -not legible issued by Dy, Director designate officer licensing & controlling authority , Drug control administration govt. of Telangana, vergalarao nagar, Hyderabad-500038 is submitted wherein it is stated that M/s Biological E. Ltd. situated at 18/1 & 3 Azamabad, Hyderabad-500020, Telangana, India is holding Drug licence. beraring r[illegible]02/HD/AP/98/V/R dated-11-12-1998 in form-28 D (Renewed in form -26 H) and valid upto 31-12-2016 issued by the drug control administration for the manufacture for sale or distribution of the drugs and cosmetics act 1940 and rules made there under. The firm is subject to periodical inspection by this dept. **the certificate is valid for one year from the date of issue**. Issue date of GMP certificate is --/10/2015 **Note:- Signature and seal of competent authority is not visible.** (pg. no.-28) (b) Self attested photo copy of letter no.-L.Dis. no-6294/stores (mfg.)/2016 dated 24-08-2016 issued to M/s Biological E. Ltd. 18/123, Azamabad, Hyderabad-500020., Telangana, India regading issued WHO By. joint Director, licensing & controlling authority, Drug control administration, Govt. of Telangana is submitted wherein it is stated that forward here with WHO, GMP certificate for the products mentioned in the joint inspection report of the officer of Drugs cohntrol administration Telengana state vide joint inspection report dt.-26-07-2016 & 27-07-2016 of deputy Drug controller (I) CDSCO, Hyderabad, It is also stated that this certificate is valid for a period of two years from date of issue. **This certificate is meant for export of drugs only.** (Pg. no.-29) (c) Self attested copy of list of six approved products under WHO-GMP Certification scheme for **export purpose** vide L. Dist. No-6294/stroes (mfg)/2016 dated Nil-08-2016 issued by joint director, licensing & controlling authority, Drug control adminsitration govt. of Telangana is submitted wherein following medicines are mentioned. (01) Tetnus vaccine (Adsorbed) I.P- 0.5 ml Ampoule. (02) Tetnus (Bett) vaccine (Adsorbed) I.P- 0.5 ml Ampoule. (03) Tetnus vaccine (Adsorbed) I.P- 5 ml vial. (04) Tetnus vaccine (Adsorbed) I.P- 5 ml vial. (05) Snake Antivenin (Polyvalent) I.P-10 ml vial. (06) Adsorbed tetnus vaccine BP-0.5 ml ampoule. In afore said letter it is also stated that (i) It is certified that the above product had been authorized to be placed on the market for use in the country under Licence no-02/HD/AP/98/V/R/R dt-11-12-1998 in form -28D valid upto 31-12-2016. (ii) The manufacturer conforms to requirements for GMP. in the manufacturer and quality control (As reccomended by the WHo) in respect of 06 (six) products to be sold or distrubuted within the country or origin (or to be exported). (iii) This certificate is valid for two years from the date of issue. [Pg. no.-29-31]
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).	Self attestedc copy of maximum jproduction capacity certificate issued vide-L.Dis. No. 15185/E(v)/TS/2015 dated -08-09-2015 by Deputy director a certifying authority Drugs control administration govt. of Telangana, is submitted wherein it is stated that maximum production capacity of Tetnus vaccine (Adsorbed) IP BETT, 0.5 ml amp. is 1,00,00,000 (one crore) per month. [Pg. no.-35]

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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 photo copy of notarised affidavit on Rs.-20/- India Non judicial stamp for non Blacklisting as per NIT Annexure-II is submitted. S. no.-82 NIT S. no.-nil Name of drug-Inj. Tetnus vaccine (Adsorbed) I.P. 0.5 ml amp. [Pg. no.-27] **Note: NIT S.no column is missing which is not accordance with NIT** (page no.27)
11	EMD details (DD number/BG number and date with issuing bank) as per Clause 3(b) .	DD NO. "232467" (BOB) `1,00,000/- Page No - 67
12	Tender Fee Rs 10,000/- in form of DD as per Clause 3(a).	DD NO. "232466" (BOB) `10,000/- Page No - 64
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-2012-13 `4,767,088,945/- Page No -39 FY-2013-14 ` 6,999,068,172/- Page No -41 FY-2014-15 `9,222,543,670/- Page No -43
14	Self attested copy of Income Tax Return for any three of last four consecutive Assessment years. As per Clause 3(m).	FY-2014-15 Page No-70 FY-2013-14 Page No- 71 FY-2012-13 Page No-72
15	Self attested copy of PAN Card of the Bidder Company. As per Clause 3(p)	PAN NO:- "AAACB 7873P" Page No-46
16	Self attested copy of Certificate of valid Sales tax/VAT registration of the bidder company. As per Clause 3(q)	TIN NO. 36270101033 Page No-73
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).	Self attested photo copy of notaorised affidavit regarding acceptance of tender conditions on Rs. 20/- Indian non judicial stamp paper as per NIT, Annexure-IV is submitted. [Pg. no.-68]

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.