S. N.	Tender Reference no.-BMSIC/DRUG/17-06 *Technical Eligibility Criteria as per NIT*	***Firm Name - M/s INDIAN IMMUNOLOGICALS LIMITED*** ***Corporate Address:- Rakshapuram, Gachibowli Post, Hyderabad - 500032, Telangana State*** ***Manufacture Unit Address:- Unit 1- Human Biologicals Institute (a division of M/s Indian Immunologicals Limited), Kozhipannai, Pudumund Post, Dr. Basavaiah Nagar, Udhagamandalam 0 643007, Tamil Nadu*** ***Unit 2 - Human Biologicals Institute (a division of M/s Indian Immunologicals Limited),Rakshapuram, Gachibowli Post, Hyderabad - 500032, Telangana State***
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) Scanned copy of Memorandum of Association of M/s Indian Immunologicals Limited is submitted. (pg. no.- 66-75) b) Scanned copy of Articles of Association of M/s Indian Immunologicals Limited is submitted. (pg. no.- 47-65) c) Scanned copy of Certificate of Incorporation (No. 01- 32666 of 1999-2000 dated 08.10.1999) of M/s Indian Immunologicals Limited is submitted. (Pg. no. -77) d) Scanned copy of typed copy of the Certified Order of High Court , Andhra Pradesh dated 6th April 2010 in the matter of Scheme of Amalgamation between Indiagen Limited and Indian Immunologicals Limited is submitted. (Pg. No. 28- 46) e) Scanned copy of Bidder Information/ Bidder details is submitted as per annexure V of NIT (Pg. No. 178) f) Scanned copy of judgement of Patna High Court against Case CWJC No. 4302 of 2010 is submitted regarding Human Biologicals Institute is a division of the Indian Immunologicals Limited. (Pg. no 179 - 185)
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.	a) Scanned copy of Certified True Copy of the Resolution Passed by the Board of Directors of Indian Immunologicals Limited on March 18, 2013 is submitted wherein it is resolved that approval of the Board be and is hereby accorded for the revised delegation of powers of Managing Director and DY. Managing Director. It is also resolved further that the Managing Director & the Dy. Managing Director be and are hereby severally authorised to sub- delegate the above said powers to any other person. b) Scanned copy of Power of Attorney given by Dr. K Anand Kumar, Managing Director, is submitted wherein it is stated that we, Indian Immunologicals Limited do hereby authorize and appoint Shri N S N Bharga, Vice President- Institution Business to be the attorney of the company to authorize of delegate any other individual as Authorised Person to submit a bid, and subsequently negotiate and sign the contracts. c) Scanned copy of Authorisation Letter (IIL/BMSICL/2017-18 dated 28th september 2017) is submitted wherein it is stated that I, N S N Bhargav, Vice President- Institutional Business do hereby authorise shri Sanjeev Kumar Thapliyal, to be the attorney of the company and to sign, submit, modify, execute, to attend and to transact the business for the Tender No. BMSICL/DRUG/17-06.
3	List of item Quoted in prescribed format as Annexure III as per Clause 3 (o)	Scanned copy of List of Items quoted is submitted as per annexure III of NIT. (Total No. of items quoted- 02) (pg. no. 132-134) Nit sl. No. Name of the Drugs specification/ Strength Pack Size Dosage form 1 Rabies Vaccine, Human IP (Cell Culture) (Lyophilised) 2.5IU 1ml vial Intramascular/ Intradermal 2 Rabies Vaccine, Human IP (Cell Culture) (Lyophilised) 2.5IU 0.5 ml vial Intramascular/ Intradermal **Note:- Quoted products mentioned at NIT sr. No. 1 & 2 are manufactured at Unit 1 and quoted product mentioned at NIT sr. No. 2 is also Manufactured at Unit 2** **(2) Column GSN Code as per annexure III of NIT is not mentioned in submitted list of items quoted (Annexure- III)**

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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.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. • 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)	**Unit-1 (situated at Kozhipannai, Pudumund)** **(a)** Scanned Copy of duplicate Manufacturing Licence in form 28 -D Gant due to Change in constitution of M/s Human Biologicals Institute (A division of Indian Immunologicals limited) issued on 13.06.2017 by Director of Drugs Control 359, Anna salai, Chennai - 600006, is submitted (Pg no. 80 -81) (b) Scanned Copy of Certificate of renewal in form 26 H issued on 12.06.2012 by Director of Drug Control I/C **359,** Anna salai, Chennai - 600006, is submitted is submitted wherein in it is stated that licence no. 15 has been renewed from **01.01.2017 to 31.12.2016 (Pg. no. 94-95)** (c) Scanned Copy of Certifiacate (L.Dis. No. 2623/D1/1/2017 dated 24.02.2017) issued by Director of Drug Control I/C 359, Anna salai, Chennai - 600006, is submitted is submitted wherein in it is stated that M/s Human Biologicals Institute (A division of Indian Immunologicals limited) bearing licence no 15 dated 06.08.1998 and valid upto 31.12.2016 and there application received for renewal for period 01.01.2017 to 31.12.2017 is under process. As per Rule 77 of Drugs & Cosmetics Rules 1945 the license shall continue to be in force until orders are passed. (Pg no. 97) **Note:- Latest Certificate of renewal in form 26 H is not submitted** (d)Products at NIT sr. No. 1 & 2 [Rabies Vaccine, Human IP (Cell Culture) (Lyophilised), 2.5IU, 1ml vial & 0.5ml] are mentioned at Sr no. 9 & Sr. no. 1 of submitted approved product list highlighted by bidder. (Pg. no. 91 & 93) **Note- i) Dosage for quoted product at NIT sl. no 2 is mentioned as 0.5 ml single immunizing dose for Intramuscular Injection or 0.1 ml dose per site for Intradermal Injection.** **ii) Dosage for quoted product at NIT sl. no 1 is mentioned as 0.1 ml dose per site for Intradermal Injection.** **iii) Approved product list for the quoted items with Brand Name is highlighted by the bidder while Approval under Generic Name is mentioned at sl. no. 10 & 2 (pg. No. 91 & 93)** (e) Scanned Copy of Market standing Certificate (L.Dis.No. 7598/01/3/17 dated 10.05.2017) issued by Director of Drugs Control 359, Anna salai, Chennai - 600006, is submitted wherein it is stated that they have manufactured and Marketed the following products for more than 3 years (Pg no. 26-27) **Unit- 2 (situated at Rakshapuram, Gachibowli)** (a) Scanned Copy of Manufacturing Licence in form 28 D issued on 16.09.2005 by Director Drugs Control Administration Govt. of Andhra Pradesh Hydrerabad is submitted wherein it is stated that licence no. 02/RR/AP/2005/V/R of M/s Human Biologicals Institute (A division of Indian Immunologicals limited) shall be in force from 17.04.2006 to 16.04.2011 (pg. no. 49) (b) Scanned Copy of Certificate of renewal in form 26 H issued on 21.07.2012 by Director of Drug Control Administration Govt. of Andhra Pradesh Hydrerabad is submitted wherein in it is stated that licence no. 02/RR/AP/2005/V/R has been renewed from 17.04.2011 to 16.04.2016 (Pg. no. 166-168) (c) Scanned Copy of Licence vality certificate (L.Dis.No. 4825/A2/2016 dated 22.04.2016) issued by Licensing & Controlling Authority, DCA, Govt. of Telegana is submitted wherein it is stated that the firm's application for nenewal of licence no. 02/RR/AP/2005/V/R is recieved on 18.03.2016 and it is under prosess as per Rule 77 of the Drugs and Cosmetics Act. It can be treated as valid till they get their renewed licence. (Pg no. 170) **Note:- Latest Certificate of renewal in form 26 H is not submitted** (d) Product at NIT sr. No. 2 (Rabies Vaccine, Human IP (Cell Culture) (Lyophilised), 2.5IU, 0.5ml vial) is mentioned at Sr no. 15 of submitted approved product list. (Pg. no. - 161) **Note- Presentation : Single Dose (0.5 ml for IM and 0.1ml for ID dose)** (e) Scanned Copy of Market standing Certificate (L.Dis.No. 8572/A2/2017 dated 07.07.2017) issued by Joint Director Licensing and Controlling Authority, DCA, Govt. of Telangana, is submitted wherein it is stated that they are manufacturing and Marketing the following products for more than 3 years (Pg. no. 25)
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
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).	(a) Scanned Copy of Non Conviction Certificate (L.Dis No. 8920/IW2/2017 dated 05.06.2017) issued by Director of Drugs Control 359, Anna salai, Chennai - 600006, is submitted wherein it is stated that M/s Human Biologicals Institute (A division of Indian Immunologicals limited) bearing licence no 15 (Unit - 1) has not been convicted in this state under the provisions of Drugs and Cosmetics Act 1940 and Rules 1945, during the preceding three years. (Pg. no 24) (b) Scanned Copy of Non Conviction Certificate (L.Dis No. 6613/A2/2017 dated 03.05.2017) issued by Joint Director, Licensing and Controlling Authority, DCA, Govt. of Telangana, is submitted wherein it is stated that M/s Human Biologicals Institute (A division of Indian Immunologicals limited) bearing licence no 02/RR/AP/2005/V/R (Unit - 2) has not been convicted in the state of Telangana during the last three financial years 2014-15, 2015-16, 2016-17, by the judicial courts for the offences under the provisions of Drugs and Cosmetics Act and Rules there under (Pg. no 23)

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) Scanned copy of Certificate of Good Manufacturing Practices (No. K Dis No. 19992/D1/2/2016 dated 13.06.2017) issued by Director of Drugs Control, 359, Anna Salai, Chennai is submitted wherein it is stated that the site indicated on this certificate i.e M/s Human Biologicals Institute (A division of Indian Immunologicals limited) bearing licence no 15 (Unit - 1) complies with Good Manufacturing Practices for the dosage forms, Vaccines. This certificate remains valid until 31.12.2018. (Pg. no. 01 -16) b) Scanned copy GMP Certificate (L. Dis. No. 9980/A2/2017 dated 06.09.2017) issued by Joint Director, Licensing and Controlling Authority, DCA, Govt. of Telangana, is submitted wherein it is stated that M/s Human Biologicals Institute (A division of Indian Immunologicals limited) bearing licence no 02/RR/AP/2005/V/R (Unit - 2) following Good Manufacturing as stipulated under the provisions of Schedule "M" of the Drugs and Cosmetics Rules 1945. This Certificate is valid for one year date of issued. (Pg. no. 145)
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) Scanned copy of Production Capacity Certificate (L. Dis. No. 4326/D1/3/17 dated 16.03.2017) issued by Director of Drugs Control 359, Anna Salai, Chennai is submitted wherein it is stated that M/s Human Biologicals Institute (A division of Indian Immunologicals limited) bearing licence no 15(Unit - 1) is a primary manufacturer whose annual capacity for the quoted items (Rabies Vaccine, Human I.P.) is 6 million vials (Pg. no. -18-20) b) Scanned copy of Production Capacity Certificate (L. Dis. No. 4798/A2/2017 dated 04.04.2017) issued by Deputy Director,& Controlling Authority, DCA, Govt. of Telangana, is submitted wherein it is stated that M/s Human Biologicals Institute (A division of Indian Immunologicals limited) bearing licence no 02/RR/AP/2005/V/R (Unit - 2), they are having annual production capacity of quoted product is 4.5 million vials. (Pg. no. - 17)
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 for non blacklisting is submitted as per annexure II of NIT (Pg. no. 135-136)
11	EMD details (DD number/BG number and date with issuing bank) as per Clause 3(b) .	BG NO -021GT02172760005 HDFC Bank `1,00,000/- Valid upto 30-06-2018 Page No:-106
12	Tender Fee Rs 10,000/- in form of DD as per Clause 3(a).	DD No:- 916410 SBI `10,000/- Page No:- 102
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 -2016-17 `5004.98 (Millions) Page No -121 FY- 2015-16 `3647.7 (Millions) Page No -117 FY 2014-15 `4751.39(Millions) Page No -116
14	Self attested copy of Income Tax Return for any three of last four consecutive Assessment years. As per Clause 3(m).	AY 2016-17 Page No -100 AY 2015-16 Page No-99 AY 2014-15 Page No -98
15	Self attested copy of PAN Card of the Bidder Company. As per Clause 3(p)	PAN No - "AAACI6620F" Page No -22
16	Self attested copy of Certificate of valid Sales tax/VAT registration of the bidder company. As per Clause 3(q)	**GSTIN NO:- "10AAACI6620F1Z9" Page No -101**
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 regarding acceptance of tender condition is submitted as per annexure IV of NIT (Pg. no. 130-131)

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. Inspite, some inadvertent dicrepencies could have been crept in. Humble request to all concerned to bring to notice in due time, if any discrepencies is observed, for rectification.

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