



(BMSIC/DRUGS/15-05)	
S. N.	<p><b>Technical Eligibility Criteria as per NIT</b></p> <p><b>Name of Bidder-M/S Reliance Life Sciences Pvt. Ltd.</b>  <b>Address: Unit I: Plant 4B, Dhirubhai Ambani Life Sciences Centre (DALC), R-282, TTC Area of MIDC, Thane, Belapur-Road, Rabale, Navi Mumbai-400701</b>  <b>Unit II: Plant 1, Sadhana Textile Mills Compound, Ground and First floor, C.S. No. 1621, Plot No. 3, Plan 1, Pandurang Budhkar Marg, Worli, Mumbai-400018</b>  <b>"Chart has been prepared on the basis of number of downloaded Pg. received (i.e.- 1-99) "</b></p>
1	<p>Constitution of the Bidding Company/Firm such as Memorandum of Association and Article of Association with complete address. As per Clause 3(c).</p> <p>Certificate of Incorporation No. U 24239 MH 2001 PTC 130654, issued by Registrar of companies Submitted (Pg. No. 65).  Reliance Life Sciences Private Limited incorporated on 13/01/2001.  List of directors Submitted (Pg. No. 64).</p>
2	<p>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> <p>Mr K.V.Subramaniam, President, authorised by Board of Directors vide resolution passed on 18/03/2015. He further authorized Mr. Vimal Singh, officer of the company, to sign all documents pertaining to tender to be submitted to BMSICL, through Notarised specific PoA. (Pg. No. 62-63).</p>
3	<p>List of item Quoted in prescribed format as Annexure III as per Clause 3 (o)</p> <p>List of items quoted are NIT S.No. 219 &amp; 221 ( <b>Total 2 items</b>) (Pg. No. 61).</p>
4	<p>• 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).  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><b>Unit I-</b> Certificate of Renewal in Form 26-I, of License No. 28E-KD/8, granted on 29/04/2009, renewed from 29/04/2014 to 28/04/2019 . Mfg. Unit Address- R-282, Plant 4A, 4B, TTC Industrial Area of MIDC, Rabale, Navi Mumbai, Distt-Thane, 400701. (Pg. No. 51)  <b>Unit II-</b> Renewal in Form 26-I of License No. 28E-3, granted on 02/11/2004, renewed from 02/11/2009 to 01/11/2014 Submitted . Mfg. Unit Address- Plant 1, Sadhana Textile Mills Compound, Ground and First floor, C.S. No. 1621, Plot No. 3, Plan 1, Pandurang Budhkar Marg, Worli, Mumbai-400018 (Pg. No. 59)  <b>Product approval :-</b>  <b>(1) NIT S.No. 219</b> (Human Normal Immunoglobulin for I.V use IP 2.5gm/50ml-50ml vial)- The product is mentioned with the heading , "List of additional products to be manufactured," stamp of Office of the Joint Commissioner, FDA, Thane, dated 15/02/2011. (<b>Unit I-</b> Plant 4B, Dhirubhai Ambani Life Sciences Centre (DALC), R-282, TTC Area of MIDC, Thane, Belapur-Road, Rabale, Navi Mumbai-400701). ( Pg. No. 48, S.No. 13)  NIT S.No. 219 is also mentioned on Pg. No. 50, in which product specification is of I.P,with issue date 02/01/2015, wherein it is mentioned the License has been renewed on 29/04/2014 and valid upto 28/04/2019, issued by Joint Commissioner (K.D.), FDA, Thane. ( Pg. No. 49-50, S.No. 68)  <b>(2) NIT S.No. 221</b> (Human Normal Immunoglobulin for I.V use IP 5gm/100ml-100ml):The product is mentioned with the heading 'List of additional products to be manufactured.' stamp of Office of the Joint Commissioner, FDA, Thane, dated 15/02/2011. (<b>Unit I-</b> Plant 4B, Dhirubhai Ambani Life Sciences Centre (DALC), R-282, TTC Area of MIDC, Thane, Belapur-Road, Rabale, Navi Mumbai-400701). ( Pg. No. 48, S.No. 14)  NIT S.No. 221 is also mentioned on Pg. No. 49, under product specification of I.P., with issue date 02/01/2015, wherein it is mentioned the License has been renewed on 29/04/2014 and valid upto 28/04/2019, issued by Joint Commissioner (K.D.), FDA, Thane. ( Pg. No. 49, S.No. 69)</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	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>Manufacturing and Marketing Certificate No. 6063379, dated 12/03/2015 by J.C, FDA, Maharashtra., Submitted stating "the above products are being marketed by the firm since last 3 years. This certificate is issued on the basis of the information provided by the manufacturer and certified by his Chartered Accountant". Quoted products are mentioned. NIT S.No. 219 and 221 are mentioned at S.No. 1 &amp; 2. <b>The certificate is of Mumbai plant (Unit II), and not of Thane plant (Unit I).</b> (Pg. No. 45)</p> <p>Another Manufacturing and Marketing Certificate No. 6063109, dated 26/02/2015 by J.C, FDA, Maharashtra., Submitted, stating "the above products are being marketed by the firm since last 3 years. This certificate is issued on the basis of the information provided by the manufacturer and certified by his Chartered Accountant". NIT S.No. 221 is mentioned on S.No. 4. <b>The certificate is for Thane plant (Unit I).</b> (Pg. No. 44)</p> <p>Production data of quoted products, issued by Chartered Accountant Submitted (Pg. No. 43).</p>
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).	<p>NCC Certificate No. 6063118, issued on 26/02/2015 by J.C, FDA, Maharashtra.. Submitted stating "Reliance Lifesciences Pvt. Ltd. or its director or any office bearer does not stand convicted at the instance of this administration under D&amp;C Act, 1940 and Rules thereunder so far". <b>The certificate is for Thane plant (Unit I).</b> (Pg. No. 39)</p> <p>Another No Conviction Certificate no. 141/14/2 dated 06/05/2014 Submitted in which it is mentioned that "they are manufacturing the drugs mentioned below for the last five years and there has been no reported case of drugs found to be not of standard quality during this period." NIT S.No. 221 is mentioned as brand name ImmunoRel 0.5gm and 5gm (10ml and 100ml). <b>The certificate is of Mumbai plant (Unit II).</b> (Pg. No. 40)</p>
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 from the last date of submission of tender. As per clause 3(j).	<p>GMP Certificate No. 5837, issued on 20/02/2014, by J.C, FDA, Maharashtra., Submitted <b>For Thane plant (Unit I).</b> wherein dosage form Injectables and Category Blood Products is mentioned with activity. Quoted products are also mentioned on Pg. No. 35, S.No. 1 and 2, with brand name ImmunoRel 2.5 g and ImmunoRel 5g (Pg. No. 35-37)</p> <p>But product specification is of <b>B.P. (Column II)</b>, as per NIT it is <b>I.P.</b></p> <p>Notarised Affidavit of GMP declaration Submitted (Pg. No. 30-31).</p> <p>GMP Certificate for <b>Worli Plant, Unit II</b>, No. 9965 dt 12.3.2015 wherein under categories of drugs Blood product is mentioned (Pg. No.33-34)</p> <p>List of product approved under WHO GMP Vide certificate No.22349 dt 10.3.2015 valid upto 9.3.2017 for Drug Licence No.3 in Form 28 E (<b>Unit II: Plant I, Sadhna textiles mill compound, Worli, Mumbai</b> Submitted, wherein the quoted product NIT Sl.no.219 is mentioned at sl.no 28. Quoted product NIT Sl.no.221 is mentioned at sl.no.29, <b>under brand name ImmunoRel 2.5g and 5g respectively, where Specification is of B.P. (Column II).</b> (Pg. No. 32)</p>
9	Self attested copies of Maximum Production Capacity Certificate (section wise) issued by concerned Licensing Authority from Drugs Control Department highlighting the quoted product section. As per Clause 3(k).	<p>Capacity and Quality Certificate No. 6064911 for <b>Unit I</b>, issued by Licensing Authority, FDA, Maharashtra, issued on 21/07/2015. Submitted On S.No. 7. "The department wise approved production capacities for the firm are as follows. The prequalified installed capacity for this firm is as follows. Annual capacity additional para: Annual capacity of our product 'Human Normal immunoglobulin for Intravenous administration I.P. 5% solution Pack size 50ml and 100ml is 9,60,000 vials/annum. (Pg. No. 26-27).</p>
10	An affidavit 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).	<p>An affidavit sworn before Notary stating that the firm &amp; its quoted product is not black listed currently (as on the 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 submitted (Pg. No. 28-29)</p>
11	EMD details (DD number/BG number and date with issuing bank) as per Clause 3(b).	<p>Rs. 1,00,000/-, BG No.- 136GM01152470003, Yes Bank</p> <p style="text-align: right;"> </p>

