

**Tender Reference no.-BMSIC/DRUG/17-07**

S. N.	<b>Technical Eligibility Criteria as per NIT</b>	<b>Firm Name - M/s Plasmagen Biosciences Pvt. Ltd.</b> <b>Corporate Address:- No. 160, KCI Chambers, 2nd Floor, Block - B, 5th Main Road, Chamarajpet, Bangalore - 560018</b> <b>Import Unit Address 1342, Block-B, 1st Floo, Dr. Shivaramkarath Nagar, MCEHS Layout, Yelahanka Hobli, Bangalore - 560064</b>																
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 Plasmagen Biosciences Pvt. Ltd. is submitted. (pg.no. 70 to 74) (b) Scanned copy of Articles of Association of M/s Plasmagen Biosciences Pvt. Ltd. is submitted. (Pg. no. 40 to 62) (c) Scanned copy of Certificate of Incorporation (no U51909KA2010PTC055077 dated 07.09.2010) of M/s Plasmagen Biosciences Pvt. Ltd. is submitted (Pg. no. -74) (d) Scanned Copy of Bidder Information/Bidder details is submitted as per annexure-V is submitted (Pg. no. 39)																
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.	Scanned Copy of Power of attorney given by Vinod Nahar, Director is submitted wherein it is stated that by virtue of the Powers vested in me by the Company during the meeting of the Board of Directors I Vinod Nahar Director of the Company do hereby Constitute, nominate and appoint Rahul K. Jain Manager- Institutional sales to do all and every act and thing whatsoever requisite and necessary to be done for Compliance with the terms and Conditions of tender reference No. BMSIC/DRUGS/17-07 (Pg. no. 2 & 3)																
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 of NIT ( Total no. of quoted items - 02) (Pg. no. 70 & 71 ) <b>Note- HSN Code is mentioned in place of GSN code in submitted list of items quoted (Annexure III).</b> <table border="1"> <thead> <tr> <th>NIT sl no.</th> <th>Name of the Drug</th> <th>Specification</th> <th>Pack Size</th> </tr> </thead> <tbody> <tr> <td>8</td> <td>Human Normal Immunoglobulin for I.V use IP</td> <td>2.5 gm/50 ml</td> <td>50 ml vial</td> </tr> <tr> <td>10</td> <td>Human Normal Immunoglobulin for I.V use IP</td> <td>5gm/100 ml</td> <td>100 ml</td> </tr> <tr> <td>13</td> <td>Rabies Immunoglobulin (Human) Injection (IP, BP, USP, EuPh, Official Compendium)</td> <td>150 IU/mL</td> <td>2 ml vial</td> </tr> </tbody> </table> <b>Note:- Name of Drug is mentioned as Human Normal Immunoglobulin for I.V use 5% IP in submitted list of items quoted (Annexure III).</b> <b>Note:- (i) Name of Drug is mentioned as Human Normal Immunoglobulin for I.V use 5% IP in submitted list of items quoted (Annexure III).</b> <b>(ii) Pack size is mentioned as 100ml vial in submitted list of items quoted (Annexure III).</b> <b>Note- (i)Name of Drug is mentioned as Human Rabies Immunoglobulin Injection EP in submitted list of items quoted (Annexure III).</b> <b>(II) dosages form is mentioned as Intramuscular in submitted list of items quoted (Annexure III).</b>	NIT sl no.	Name of the Drug	Specification	Pack Size	8	Human Normal Immunoglobulin for I.V use IP	2.5 gm/50 ml	50 ml vial	10	Human Normal Immunoglobulin for I.V use IP	5gm/100 ml	100 ml	13	Rabies Immunoglobulin (Human) Injection (IP, BP, USP, EuPh, Official Compendium)	150 IU/mL	2 ml vial
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13	Rabies Immunoglobulin (Human) Injection (IP, BP, USP, EuPh, Official Compendium)	150 IU/mL	2 ml vial															

*L. Sridhar*      *AK*      *Anand*      *ak (11-16)*      *sdh*

- 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 DCGI 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)

N/A

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*Capricorn*

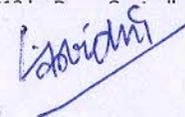
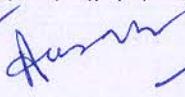
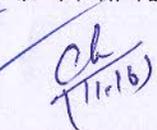
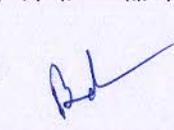
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*Ch  
(11-16)*

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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) Scanned copy of Import Licence in Form 10 issued on 06.03.2014 by DCG(I) is submitted wherein it is stated that Licence No. BP-13-114 shall be in force from 06.03.2014 to 30.04.2015 and name of drugs imported is mentioned as **Anti Rabies Immunoglobulin IM- I.P.** (Pg. no.-113-114)  
**Note- NIT requirement is Rabies Immunoglobulin (Human) Injection,(IP, BP, USP, EuPh, Official Compendium), 150 IU/mL, 2 ml vial and import licence is valid upto 30.04.2015**
- b) Scanned copy of Import Licence in Form 10 issued on 21.06.2017 by Joint, Drugs Controller (India) is submitted wherein it is stated that Licence No. BP-82-223 shall be in force from 21.06.2017 to 14.05.2020 and name of drugs imported is mentioned as **Human Normal Immunoglobulin for IV administration 5% I.P.** (Pg. no.-112)  
**Note- NIT requirement is Human Normal Immunoglobulin for I.V use IP, 2.5 gm/50 ml, 50 ml vial or 5gm/100ml, 100ml.**
- c) Scanned copy of Import Licence in Form 10 issued on 06.01.2016 by Deputy, Drugs Controller (India) is submitted wherein it is stated that Licence No. BP-74-193 shall be in force from 06.01.2016 to 30.11.2018 and name of drugs imported is mentioned as **Human Normal Immunoglobulin for Intrevenous administration I.P. 5gm in 100 ml and 2.5 gm in 50 ml** (Pg. no.-111)
- d) Scanned copy of Import Licence in Form 10 issued on 13.04.2015 by Drugs Controller General (India) is submitted wherein it is stated that Licence No. BP-58-164 shall be in force from 13.04.2015 to 04.03.2018 and name of drugs imported is mentioned as **Human Normal Immunoglobulin for Intravenous administration I.P. (5 gm in 100 ml glass bottle and 2.5 gm in 50 ml glass vial)** (Pg. no.-110)
- e) Scanned copy of Import Licence in Form 10 issued on 27.08.2012 by Drugs Controller General (India) is submitted wherein it is stated that Licence No. BP-58-78 shall be in force from 27.08.2012 to 04.03.2015 and name of drugs imported is mentioned as **Human Normal Immunoglobulin for Intravenous administration I.P. 5 gm in 100 ml bottle and 2.5 gm in 50 ml glass vial.** (Pg. no.-109)  
**Note:- Import Licence is valid upto 04.03.2015**
- f) Scanned copy of Import Licence in Form 10 issued on 13.04.2015 by Drugs Controller General (India) is submitted herein it is stated that Licence No. BP-13-163 shall be in force from 13.04.2015 to 30.05.2018 and name of drugs imported is mentioned as **Anti-Rabies Immunoglobulin IM ( Plasma RAB)-EP** (Pg. no.-115)  
**Note- NIT requirement is Rabies Immunoglobulin (Human) Injection,(IP, BP, USP, EuPh, Official Compendium), 150 IU/mL, 2 ml vial**
- g) Scanned copy of Registration Certificate in Form 41 issued on 15.05.2017 by DCG(I) is submitted wherein it is stated that Registration certificate no. BP-82 shall be in force from 15.05.2017 to 14.05.2020. (Pg. no. 104)
- h) Scanned copy of Registration Certificate in Form 41 issued on 07.12.2015 by Joint Drugs Controller (India) is submitted wherein it is stated that Registration certificate no. BP-74 shall be in force from 01.12.2015 to 30.11.2018. (Pg. no.- 102-103)  
**Note- This Registration Certificate is issued through the office of the manufacturer or his Authorised agent in India M/s Reliance Life Sciences Pvt. Ltd, Thane.**
- i) Scanned copy of Registration Certificate in Form 41 issued on 27.02.2015 by Drugs Controller General (India) is submitted wherein it is stated that Registration certificate no. BP-58 shall be in force from 05.03.2015 to 04.03.2018. (Pg. no.- 100-101)
- j) Scanned copy of Registration Certificate in Form 41 issued on 05.03.2012 by Drugs Controller General (India) is submitted wherein it is stated that Registration certificate no. BP-58 shall be in force from 05.03.2012 to 04.03.2015. (Pg. no.- 98-99)  
**Note- This Registration Certificate is issued through the office of the manufacturer or his Authorised agent in India M/s Claris Lifesciences Limited, Ahmedabad and it is valid up to 04.03.2015.**

*Labichini*     

04.03.2015.

k) Scanned copy of Registration Certificate in Form 41 issued on 19.03.2012 by Drugs Controller General (India) is submitted wherein it is stated that Registration certificate no. BP-13 shall be in force from 01.05.2012 to 30.04.2015. (Pg. no.- 96-97)

**Note- This Registration Certificate is issued through the office of the manufacturer or his Authorised agent in India M/s Synergy Diagnostics Pvt. Ltd. and it is valid up to 30.04.2015.**

l) Scanned copy of Registration Certificate in Form 41 issued on 17.02.2015 by Drugs Controller General (India) is submitted wherein it is stated that Registration certificate no. BP-13 shall be in force from 01.05.2015 to 30.04.2018. (Pg. no.- 94-95)

**Note- This Registration Certificate is issued through the office of the manufacturer or his Authorised agent in India M/s Trigenesis Life science Pvt. Ltd., Bangalore.**

m) Scanned copy of Licence to Sell in Form 20B and 21B issued on 07.10.2011 by Licensing Authority & Assistant Drugs Controller, DCA, Bangalore Circle 1 is submitted wherein it is stated that Licence no. KA-B01-100007 & KA-B01-100008 shall be in force from 07.10.2011 to 06.10.2016 (Pg. no. 106-107)

n) Scanned copy of Certificate of Renewal in Form 21 C issued on 29.09.2016 by Assistant Drugs Controller & Licensing Authority, DCA, Bangalore Circle 5- ADC2 is submitted wherein it is stated that Licence no. KA-B01-100007 & KA-B01-100008 has been renewed from 07.10.2016 to 06.10.2021 (Pg. no. 108)

o) Scanned copy of several invoices is submitted by bidder details are as follows.

Invoice no. and date	NIT sl. no of the	Page no.
	Product mentioned in invoice	
SKP 101612001 dt 12.12.2016	10	91
SKP 202508001 dt 27.08.2015	10	90
4000010879 dt 02.10.2014	10	89
4000004161 dt 26.12.2012	10	88
1 dt 25.07.2017	10	86,87
1011622 dt 29.05.2014	13	85
1013048 dt 16.06.2015	13	84
1014924 dt 25.12.2016	13	82

**Note- Invoice regarding importing for the product at NIT sl. no. 8 is not 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)

Scanned copy of Market Standing Certificate (No.: DCD/SPL-CL-1/CR-324/17-18 dated 19.06.2017) issued by Drugs Controller & Licensing Authority, DCA, Govt. of Karnataka is submitted wherein it is stated that the firm is importing and marketing the following products for the year 2014-15, 2015-16 & 2016-17. This certificate is valid for one year from the date of issue. (Pg. no. 105)

**Note-i) Market standing Certificate for the product at NIT sl. no. 8 is not submitted by bidder.**

**ii) This certificate is issued for participation in tender called by Deputy Director of Health Services (E&S), West Bengal.**

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).

Scanned copy of No Conviction Certificate (No. DCD/Spl. C1-1/CR-801/17-18 dated 22.08.2017) issued by Deputy Drugs Controller, DCA, Govt. of Karnataka is submitted wherein it is stated that the said Licensee has not been convicted in Karnataka for the violation of provisions of the Drugs and Cosmetics Act, 1940 and Rules thereunder, during the preceding three years. (Pg. no.- 6)

**Note- This certificate is issued for the purpose of participation in the tender floated by Rajasthan Medical Services Corporation Ltd., Jaipur.**

*Chandana*  
*AD*  
*Amrinder*  
*ck*  
*(11/16)*  
*Bl*

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>a) Scanned copy of Certificate of GMP Compliance (037/2016/SAUMP/GMP valid till 20.04.2019) for M/s BIOFARMA PLASMA Limited Liability Company, Ukraine, signed by Executive Officer, State Administration of Ukraine on Medicinal Products is submitted. (Pg. no.-131-133)</p> <p>b) Scanned copy of Certificate of A Pharmaceutical Product (No. CPP/UA/01/17 valid until 15.07.2020) M/s BIOFARMA PLASMA Limited Liability Company, Ukraine, issued by Head of the State Service of Ukraine on Medicines and Drugs Control is submitted. (Pg. no-129-130)</p> <p>c) Scanned copy of Certificate of Good Manufacturing Practice issued on 11.06.2015 by Gyeongin Regional Food and Drug Administration, Korea for M/s S K Plasma Co. Ltd., Korea is submitted. (Pg. no. 128)</p> <p>d) Scanned copy of Certificate of a Pharmaceutical Product ( No. 2015-A1-0695 dated 29.05.2015) issued by Director, Biologics Division Biopharmaceuticals &amp; Herbal Medicine Evaluation Department, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Korea for M/s S K Plasma Co. Ltd., Korea is submitted. (Pg. no. 125-127)</p> <p>e) Scanned copy of Certificat (No. GMP 62.3) of GMP Compliance of a Manufacturer (KAMADA LTD, ISRAEL) signed on 07.04.2016 by Pharmacist, GMP Inspector, Israel is submitted. (Pg. no.-121-124)</p> <p>f) Scanned copy of Certificate of A Pharmaceutical Product (No. p34/17 valid until 25.05.2019) M/s KAMADA LTD, ISRAEL, issued by Registration Department, Pharmaceutical Administration, Ministry of Health, Jerusalem, Israel is submitted. (Pg. no 120)</p> <p><b>Note- GMP Compliance/ Copp of the manufacturing company m/s SK Chemicals Co. Ltd. Korea is not submitted.</b></p>												
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 Notarised affidavit for Importing Capacity along with several Invoices is submitted wherein it is stated that the company has Adequate importing capacity for requirement laid in Tender Ref. no. BMSIC/DRUGS/17-07 (Pg. no.- 82-92)												
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	Scanned copy of notarised affidavit for non blacklisting is submitted as per annexure II of NIT. (Pg. no. 8-9)												
11	EMD details (DD number/BG number and date with issuing bank) as per	DD No - "120146" `1,00,000/- Dated 06-10-2017 Bank of India Page No -135												
12	Tender Fee Rs 10,000/- in form of DD as per Clause 3(a).	DD No - "120152" `10,000/- Dated 06-10-2017 Bank of India Page No -135												
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)	<table border="0"> <tr> <td>FY-2015-16</td> <td>`29.10 (Crores)</td> <td>FY-2013-14</td> <td>`19.22 (Crores)</td> <td>FY-2014-15</td> <td>`32.14 (Crores)</td> </tr> <tr> <td>Page No -141</td> <td></td> <td></td> <td></td> <td>Page No -138</td> <td></td> </tr> </table>	FY-2015-16	`29.10 (Crores)	FY-2013-14	`19.22 (Crores)	FY-2014-15	`32.14 (Crores)	Page No -141				Page No -138	
FY-2015-16	`29.10 (Crores)	FY-2013-14	`19.22 (Crores)	FY-2014-15	`32.14 (Crores)									
Page No -141				Page No -138										
14	Self attested copy of Income Tax Return for any three of last four consecutive Assessment years. As per Clause 3(m).	<table border="0"> <tr> <td>AY -2016-17</td> <td>Page No -80</td> <td>AY-2015-16</td> <td>Page No -78</td> </tr> <tr> <td>Page No -79</td> <td>AY-2014-15</td> <td></td> <td></td> </tr> </table>	AY -2016-17	Page No -80	AY-2015-16	Page No -78	Page No -79	AY-2014-15						
AY -2016-17	Page No -80	AY-2015-16	Page No -78											
Page No -79	AY-2014-15													
15	Self attested copy of PAN Card of the Bidder Company. As per Clause 3(p)	PAN No -"AAFCP7887E" Page No -4												

16	Self attested copy of Certificate of valid Sales tax/VAT registration of the bidder company. As per Clause 3(g)	GSTIN - "29AAFCP788" <i>7E1ZT</i> <i>Chavala</i>	(By Soft Copy )
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. 146-147)	

The facts in clause No-1 to 10 and 17 of the provided sheet has been compiled with due diligence and care, on the basis of document provided by BMSICL. Inspite, some inadvertent discrepancies could have been crept in. Humble request to all concerned to bring to notice in due time, if any discrepancies is observed, for rectification.

*Chavala*      *RV*      *Arun*      *Ch*  
*(1/1/16)*      *Red*