Tender Reference no.-BMSIC/DRUGS/18-03

S.N.	Technical Eligibility Criteria as per NIT	***Firm Name - M/S Saar Biotech*** ***Corporate Address: - Sco-165 1st floor, Sector -38, Chandigarh*** ***Manufacturer Address:- Vill- BHU, NH-21-A Nalagarh Road, Distt. Solan (H.P) - 173205***
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 Partnership Deed submitted in which J. N . Gupta , V.P.Agrawal, Radheshyam Goyal and Saurabh Gupta are mentioned as partners. Partnership deed executed on 23 march 2006. (Pg. No.-9 to 12) (b) Scanned copy of Bidder Information/ Bidder details is submitted as per Annexure V of NIT. (Pg. No.-75-76)
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 Resolution by the Partners is submitted wherein it is resolved in the meeting of Partners held on 20.10.2005 of M/S Saar Biotech that Mr.J.N.Gupta (Partner) will be appointed as occupier of the factory and authorised **to sign all the documents related to under Factories Act, 1948.** (pg. no.62) (b) Scanned copy of letter regarding Authorisation Letter to sign the tender documents is submitted wherein it is stated that Mr. J. N . Gupta partner authorised to Mr. Keshav Kumar to sign the all documents of above refered tender as BMSIC/DRUGS/18-03. (Pg. no- 74) **Note- It is not clear from the submitted documents whether Mr. J. N. Gupta can delegate the power to Mr. Keshav Kumar.**
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-05) (Pg. no-59)

NIT Sl. No.	Name of Drug	Specification /strength	Pack Size
40	Levocetrizine Dihydrochloide syrup	Each 5ml contains Levocetrizine Dihydrochloide IP 2.5mg	30ml Bottle
41	Iron and Folic Acid Syrup IP	Each 5ml contains Ferrous Sulphate equivalent to 100 mg of elemental ferrous iron & 0.5 mg of folic Acid (To be labelled as per Schedule V)	200 ml Bottle
44	Miconazole Cream IP	2% w/w	15 gm tube
48	Diclofenac Gel	1% w/w	30 gm
49	Paracetamol Syrup IP	125 mg/ 5ml	60 ml

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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	(a) Scanned Copy of Manufacturing Licence in Form 25 [**Licence to Manufacture for sale of drugs other than those specified in schedules C and C(1)**] issued on 23.09.2005 by Drug Controlling- Cum- Licensing Authority Shimla (H.P.) is submitted wherein it is stated that Licence No. MNB/05/191 of M/s Saar Biotech, Bhud, Tehsil- Nalagarh shall be in force from 23.09.2005 to 22.09.2010 (Pg. no. 40) **Note- Submitted Manufacturing Licence in Form-25 which is not in accordance to Drugs and Cosmetics Act 1940 - "Licence to manufacture for sale or for distribution of] drugs other than those specified in [Schedules C and C(1) and X] "** (b) Scanned Copy of Manufacturing Licence in Form 28 issued on 23.09.2005 by Drug Controlling- Cum- Licensing Authority Shimla (H.P.) is submitted wherein it is stated that Licence No. MB/05/192 of M/s Saar Biotech, Bhud, Tehsil- Nalagarh shall be in force from 23.09.2005 to 22.09.2010 (Pg. no. 39) (c) Scanned Copy of Certificate of Renewal in Form 26 issued on 19.11.2011 by State Drug Controller, Controlling Cum- Licensing Authority Baddi (H.P.) is submitted wherein it is stated that Licence No. MNB/05/191 & MB/05/192 of M/s Saar Biotech, Bhud, Tehsil- Nalagarh has been renewed from 23.09.2010 to 22.09.2015 (Pg. no. 43) (d) Scanned Copy of Certificate of Renewal in Form 26 (**Certificate of Renewal of Licence to Manufacture for sale of Drugs those specified in Schedule X**)issued on 09.11.2015 by State Drug Controller, Controlling Cum- Licensing Authority Baddi (H.P.) is submitted wherein it is stated that Licence No. MNB/05/191 & MB/05/192 of M/s Saar Biotech, Bhud, Tehsil- Nalagarh has been renewed from 23.09.2015 to 22.09.2020 (pg. no. 44) **Note- Submitted Certificate of Renewal in Form- 26 which is not in accordance to Drugs and Cosmetic Act 1940 "Certificate of Renewal of Licence to Manufacture for sale of Drugs other than those specified in Schedule X"** Approved product list:- (e) Scanned copy list of additional product to be manufactured by M/S Saar Biotech, Baddi, HP under Drug licence no-MNB/05/191 and MB/05/192 on form 25 & 28 valid upto 22-09-2020 is signed on 19.09.2011, 13.03.2012, 06.10.2008, 21.05.2011 & 28.06.2007 by State drug controller, Controlling - cum licensing authority, Baddi solan (H.P.) is submittted. (pg. no. 35 to 38) NIT Sl. No. Name of Drug Page No. 40 Brand Name- **NUCET for the company INTAS** 38 41 Brand Name- **FEROMUS-F for the company OPTIMUS** 37 **with composition- Each 5 ml contains Ferrous Sulphate eq. to iron- 20 mg** **NOTE: 1) NIT requirement is Each 5 ml contains Ferrous Sulphate eq. to iron- 100 mg** **2) Product approval is submitted in Brand Name without IP specification.** 44 Brand Name- **RING GONE for the company RING GUARD** 36 48 Brand Name- **DIFAN for the company DICLOMAX TORRANT** 33 **Note- Composition of DIFAN is mentioned as Diclofenac Diethylamine BP Equiv. to Diclofenac Sodium (hand written) IP. Diclofenac Diethylamine BP cannot be made equivalent to Diclofenac Sodium IP** 49 Brand Name- **T-QUIT for the company PACIFIC THERAPEUTICS** 35

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	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)	(f) Scanned copy list of additional product to be manufactured by M/S Saar Biotech, Baddi, HP under Drug licence no-MNB/05/191 and MB/05/192 on form 25 & 28 valid upto 22-09-2020 is signed on 09.11.2015 by State drug controller, Controlling - cum licensing authority, Baddi solan (H.P.) is submittted. (pg. no. 29 to 34) NIT Sl. No. Name of Drug Page No. 40 Levocetirizine Hcl Syrup 32 & 34 41 Ferrous Sulphate & Folic Acid Syrup **without IP specification** 31 **with composition- Each 5 ml contains Ferrous Sulphate eq. to iron- 20 mg** **NOTE: 1) NIT requirement is Each 5 ml contains Ferrous Sulphate eq. to iron- 100 mg (for NIT sl. no. 41)** **2) Product approval is submitted in Brand Name without IP specification.** 44 Miconazole Nitrate Cream IP 30 48 Diclofenac Gel BP 29 **Note- Composition of Diclofenac Gel BP is mentioned as Diclofenac Diethylamine BP Equiv. to Diclofenac Sodium IP. Diclofenac Diethylamine BP cannot be made equivalent to Diclofenac Sodium IP** (g) Scanned copy list of additional product to be manufactured by M/S Saar Biotech, Baddi, HP under Drug licence no-MNB/05/191 and MB/05/192 on form 25 &28 signed on 25.04.2016 by State drug controller, Controlling - cum licensing authority, Baddi solan HP. is submittted. (pg. no. 28) 49 Paracetamol Syrup IP 28 **Note-i) Name of quoted drug (i.e. approval in Generic Name) is not mentioned in old approved list and approval is granted for different company.** **ii) The New approval date is 09.11.2015 with Generic Name which does not comply 3(f) - Approved product list as per the license issued for quoted drugs for minimum three years.** **iii) Pack size is not mentioned in approved product list.** (I) Scanned Copy of Manufacturing & Market Standing Certificate (No. HFW-H(Drugs) 254/05 dated 28.02.2018) issued by State drug controller, Controlling - cum licensing authority, Baddi solan HP. dated on 28.02.2018) is submittted wherein it is stated that M/S Saar Biotech, Baddi, HP is holding valid manufactruring License No.Drug licence no-MNB/05/191 and MB/05/192 on form 25 &28 respectively are manufactring & marketing the following drugs since last three years. Composition of the product at NIT sl. no. 40, 41, 44,48 & 49 are mentioned in the Name of product Column in above certificate. (Pg. no. 18-21)
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)	NA
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)	NA

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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 (No HFW-H()drugs)254/05(Vol.II) dated 02.05.2016) issued by State drug controller, Controlling - cum licensing authority, Baddi solan HP. is submittted wherein it is stated that M/s Saar Biotech bearing Drug Licence no. MNB/05/191 and MB/05/192 granted on 02-05-2016 in form 25 & 28 and firm has not been convicted by a court of Law in this state under the drug and cosmectic Act. 1940 and Rules made thereunder during the preceding three years (Pg. no-14) (b)Scanned copy of Non Conviction Certificate (No HFW-H()drugs)254/05(Vol.IV) dated 17.04.2017) issued by State drug controller, Controlling - cum licensing authority, Baddi solan HP. is submittted wherein it is stated that M/s Saar Biotech bearing Drug Licence no. MNB/05/191 and MB/05/192 granted on 17.04.2017 in form 25 & 28 valid upto 22-09-2020 and firm has not been convicted by a court of Law in this state under the Drugs and Cosmetic Act and the Rules. (Pg. no-15) (c)Scanned copy of Non Conviction Certificate (No HFW-H()drugs)254/05(Vol.IV) dated 16.01.2018) issued by State drug controller, Controlling - cum licensing authority, Baddi solan HP. dated is submittted wherein it is stated that M/s Saar Biotech bearing Drug Licence no. MNB/05/191 and MB/05/192 granted on 16.01.2018 in form 25 & 28 valid upto 22-09-2020 and firm has not been convicted by a court of Law in this state under the Drugs and Cosmetics Act and the Rules during the preceding three years. (Pg. no-16)
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).	Scanned copy of G.M.P. Certificate (No HFW-H (Drugs) 254/05 dated 24.01.2018) issued by state Drugs Controller Controlling cum Licensing Authority, Baddi, Solan (H.P) is submitted wherein it is stated that M/s Saar Biotech is following Good Manufacturing Practices as stipulated under the provisions of Revised Schedule "M" of Drugs & Cosmetics Rules, 1945 in respect of category of Drugs Liquid Orals, Ointments & Dry Syrups. This certificate is valid for the period of two years from the date of issue. (pg. no. - 25)
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 Capacity Assesment Certificate (No-HFW-H (Drugs) 254/05 dated10.01.2012) issued by State Drug Controller, Controlling cum Licensing Authority, Baddi, Solan (H.P) is submitted wherein Capacity of M/s Saar Biotech on single shift is mentioned as for liquid section -104 million pcs, ointment -54 million pcs and dry syrup - 45 million pcs (Pg. No. - 8)
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 (signed by Mr. Jagan NathGupta, partner) is submitted as per Annexure II of NIT . (Pg. No. -57 to 58) **Note- Submitted affidavit is not signed by Authorised person Mr. Keshav Kumar.**
11	EMD details (DD number/BG number and date with issuing bank) as per Clause 3(b) .	AXIS BANK D.D no:-"005451" Rs.1,00,000/- Pgno:-27
12	Tender Fee Rs 10,000/- in form of DD as per Clause 3(a).	AXIS BANK D.D no:-"005450" Rs.10,000/- Pgno:-26
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)	F.Y.-2014-2015 Rs.65.64 (in crore) Pgno:-54 F.Y.-2015-2016 Rs.51.25 (in crore) Pgno:-51 F.Y.-2016-2017 Rs.15.10 (in crore) Pgno:-48

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14	Self attested copy of Income Tax Return for any three of last four consecutive Assessment years. As per Clause 3(m).	F.Y.-2014-2015 Pgno:-22 F.Y.-2015-2016 Pgno:-23 F.Y.-2016-2017 Pgno:-24
15	Self attested copy of PAN Card of the Bidder Company. As per Clause 3(p)	PAN no:-"ABDFS5745G" Pgno:-13
16	Self attested copy of Certificate of valid Sales tax/VAT registration of the bidder company. As per Clause 3(q)	Submitted Pgno:-86
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 (signed by Mr. Jagan NathGupta, partner) is submitted as per annexure IV of NIT. (Pg. no- 60 to 61) **Note- Submitted affidavit is not signed by Authorised person Mr. Keshav Kumar.**
	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 discrepencies could have been crept in. Humble request to all concerned to bring to notice in due time if any discrepencies are observed for rectification.	

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