

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

S.N.	Technical Eligibility Criteria as per NIT	Firm Name - M/S Ornate Labs Ltd. Corporate Address :- Industrial Estate, Beta Muzaffarpur - 842005 Manufacturer Address :- Industrial Estate, Beta Muzaffarpur - 842005
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 dated 03.02.2000 of M/s Ornate Labs Private Limited is submitted. (Pg. no 36-42) b) Scanned copy of Articles of Association dated 03.02.2000 of M/s Ornate Labs Private Limited is submitted. (Pg. no 20-35 & 109-129) c) Scanned copy of Certificate of Incorporation(No. 03-09147 of 1999-2000 dated 03.02.2000) of M/s Ornate Labs Private Limited is submitted. (Pg. no 43) d) Scanned copy of Bidder Information/ Bidder details is submitted as per annexure V of NIT. (Pg. no- 106) e) Scanned copy of list of Directors is submitted. (Pg. no 105)
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 Extract of Minute's of the Board of Directors of M/s Ornate Labs Pvt. Ltd. held on 24.04.2018 is submitted wherein it is stated that Mr. Sanjiv Rai, Managing Director is being hereby authorized to purchase the tender paper in the name of company, submit the tender, sign the documents on behalf of the company and to transact the business with Office of BMSICL. (Pg. no-88)
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.) NIT S. No. Name of the Drug specification pack size 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 49 Paracetamol Syrup IP 125 mg/ 5ml 60 ml

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- 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

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14/06/18

PK
12/06/18

Yojir
12/06/18

Vijay Kumar
12/06/18

Sumit
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Om
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AS
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Ad
12/06/2018

- Scanned copy of Manufacturing Licence in Form 25 issued on 30.03.2000 by State Drugs Controller-Cum- Chief Licensing Authority, Bihar, Patna is submitted wherein it is stated that Licence no. 1419/2000 of M/s Ornate Labs. Private Limited shall be in force from 30.03.2000 to 31.12.2001. (Pg. no-79)
 - Scanned copy of Manufacturing Licence in Form 28 issued on 30.03.2000 by State Drugs Controller-Cum- Chief Licensing Authority, Bihar, Patna is submitted wherein it is stated that Licence no. 1418/2000 of M/s Ornate Labs. Private Limited shall be in force from 30.03.2000 to 31.12.2001. (Pg. no-78)
 - Scanned copy of Certificate of Renewal in form 26 issued on 02.05.2012 by State Drugs Controller-Cum- Chief Licensing Authority, Bihar, Patna is submitted wherein it is stated that Licence no. 1418/2000 of M/s Ornate Labs. Private Limited has been renewed form 01.01.2012 to 31.12.2016 (Pg. no-55-56)
 - Scanned copy of Certificate of Renewal in form 26 issued on 02.05.2012 by State Drugs Controller-Cum- Chief Licensing Authority, Bihar, Patna is submitted wherein it is stated that Licence no. 1419/2000 of M/s Ornate Labs. Private Limited has been renewed form 01.01.2012 to 31.12.2016 (Pg. no-57-58)
 - Scanned copy of Certificate [File No. -15/Au-09-9/2000 (Part) 385(15)/H dated 24.04.2017] issued by State Drugs Controller -Cum- Chief Licensing Authority, Bihar, Patna is submitted wherein it is stated that M/s Ornate Labs Pvt. Ltd, has already applied the application for renewal for further period from dated 01.01.2017 to 31.12.2021. The firm has also submitted application for GMP, GLP & No Conviction Certificate. The Manufacturing Licence no. 1418/00 in Form 28 & Licence No. 1419/00 in Form 25 shall continue to be in force until order are passed on the renewal application. (Pg. no-77)
 - Scanned copy of Certificate [File No. -15/Au-09-9/2000 (Part) 863(15)/H dated 08.09.2017] issued by State Drugs Controller -Cum- Chief Licensing Authority, Bihar, Patna is submitted wherein it is stated that M/s Ornate Labs Pvt. Ltd, has already applied the application for renewal for further period from dated 01.01.2017 to 31.12.2021. The firm has also submitted application for GMP, GLP & No Conviction Certificate. The Manufacturing Licence no. 1418/00 in Form 28 & Licence No. 1419/00 in Form 25 shall continue to be in force until order are passed on the renewal application. (Pg. no-76)
 - Scanned copy of Approved Product list is submitted along with form 26 (signed on 02.05.2012) Quoted product details are as follows.
 - Bidder has submitted approved product list in which at sl. no 26 product name is mentioned as **Duragesic Syrup** while NIT requirement at sl. no. 49 is Paracetamol Syrup IP (Pg. No. 54)
- Note- product is approved in brand name.**
- Scanned copy of Additional Approved Product list signed on 02.04.2013 is also submitted.
 - Bidder has submitted approved product list in which at sl. no 8 product name is mentioned as Paracetamol Syrup **without IP Specification** while NIT requirement at sl. no. 49 is Paracetamol Syrup IP (Pg. No. 52)
- Note- Product is approved without IP specification.**
- Scanned copy of Additional Approved Product list signed on 19.01.2015 is submitted.
 - Bidder has submitted approved product list in which at sl. no 41 product name is mentioned as Iron & Folic Acid Syrup **without IP Specification**

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 (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)

Note -NIT requirement at sl. no. 41 is Iron & Folic Acid Syrup IP

(Pg. No. 50)

j) Scanned copy of Additional Approved Product list signed on 04.04.2018 is also submitted

D) Bidder has submitted approved product list in which at sl. no 1 product name is mentioned as Iron & Folic Acid Syrup IP

(Pg. No. 49)

(j) Scanned copy of Manufacturing and Marketing Certificate (Memo No- 15/Au 9-09/2000 474(15)/H dated 31.05.2017) issued by State Drugs Controller-Cum-Chief Licensing Authority, Bihar, Patna is submitted wherein it is stated that M/s Ornate Labs. Private Limited is manufacturing the following products more than three years. This is further certified that the above said products are also being marketed by them from more than three years.

Quoted products at NII s.no. 41 & 49 are mentioned at sl. no. 18 & 20 respectively with brand & generic Name without IP specification. (Pg. no 45-48)

Note- As per para 3 (iv) of Sankalp No. 675(1) dated 09.09.2013 issued by Joint Secretary, Health Dept., Govt. of Bihar the submitted market standing certificate is not for current year. (present year)

(f) Scanned copy of certificate (Memo No. 106 dated 09.04.2018) issued by Inspector of Drugs Muzaffarpur-1 is submitted wherein it is stated that the manufacturing unit is in working condition and manufacturing process is going on. (Pg. no-98)

j) Scanned copy of Acknowledgement by Executive Director, Regional office, Muzaffarpur is submitted wherein Entrepreneurs Number is mentioned as 1014 12 0039P.
(Pg. no-101-102)

(k) Scanned copy of Certificate (Memo No 496 dated 09.04.2018) issued by Executive Director, Bihar Industrial Area development authority, Muzaffarpur is submitted wherein it is stated that the registration of the firm has never been cancelled, suspended or withdrawn and the unit is running well. (Pg. no. 99)

1) Scanned copy of Sankalp (No. 675/1) dated 09.09.2013 issued by Joint Secretary, Govt. of Bihar is also submitted by bidder. (Pg. no. 13-16)

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

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

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 Non Conviction Certificate (No 15/Au-09-9/2000 (Part-1) 878(15)/H dated 21.09.2017) issued by State Drugs Controller-Cum- Chief Licensing Authority, Bilhar, Patna is submitted wherein it is stated that M/s Ornate Labs. Private Limited bearing Licence no. 1418/00 & 1419/00 has not been convicted for preceding three years by courts of law in this state under the provisions of Drugs and Cosmetics Act, 1940 and Rules made there under. (Pg. no-19)
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Scanned copy of Non Conviction Certificate (No 15/Au-09-9/2000 (Part-1) 878(I5)/H dated 21.09.2017) issued by State Drugs Controller-Cum- Chief Licensing Authority, Bihar, Patna is submitted wherein it is stated that M/s Ornate Labs. Private Limited bearing Licence no. 1418/00 & 1419/00 has not been convicted for preceding three years by courts of law in this state under the provisions of Drugs and Cosmetics Act, 1940 and Rules made there under. (Pg. no-19)

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(i).

Scanned copy of GMP Certificate (No 15/Au-09-9/2000 (Part-1) 890(15)/H dated 26.09.2017) issued by State Drugs Controller-Cum- Chief Licensing Authority, Bihar, Patna is submitted wherein it is stated that M/s Ornate Labs. Private Limited bearing licence no. 1418/2000 & 1419/2000 is following the requirements of Good Manufacturing Practices as per the provisions of revised Schedule M of the Drugs and Cosmetics Act, 1940 and Rules there under. This certificate is valid for a period of one year from the date of its issue. (Pg. no-87)

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9	If 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 Production Capacity Certificate (No 15/Au-09-9/2000 (Part-1) 714(15)/H dated 23.05.2012) issued by State Drugs Controller-Cum- Chief Licensing Authority, Bihar, Patna is submitted wherein it is stated that Manufacturing capacity of Liquid section (Oral) of M/s Ornate Labs. Private Limited is mentioned as (8 hours schedule) 4400 Ltrs. (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 97)
11	EMD details (DD number/BG number and date with issuing bank) as per Clause 3(b).	EMD Exempted Pgeno:-16
12	Tender Fee Rs 10,000/- in form of DD as per Clause 3(a).	AXIS BANK D.D no:-"003509" Rs.10,000/- Pgeno:-01
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.10.78(in crore) Pgeno:-93 F.Y.-2015-2016 Rs.10.62(in crore) Pgeno:-91 F.Y.-2016-2017 Rs.10.72(in crore) Pgeno:-89
14	Self attested copy of Income Tax Return for any three of last four consecutive Assessment years. As per Clause 3(m).	F.Y.-2015-2016 Pgeno:-84 F.Y.-2016-2017 Pgeno:-83 F.Y.-2017-2018 Pgeno:-82
15	Self attested copy of PAN Card of the Bidder Company. As per Clause 3(p)	PAN no:- "AACCM6171D" Pgeno:-18
16	Self attested copy of Certificate of valid GST registration of the bidder company. As per Clause 3(q)	Submitted Pgeno:-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 is submitted as per annexure IV of NIT. (Pg. no- 96)
	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 are observed for rectification.	

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