Tender Reference no.- BMSIC/DRUG/16-07

S.N.	Technical Eligibility Criteria as per NIT	Firm Name - M/s Kwality Pharmaceuticals Ltd. Corporate Address: 6th Mile Stone, Village Nag Kalan, Majitha Road, Amritsar-143601 (India) Manufacturing Unit Address:-6th Mile Stone, Village Nag Kalan, Majitha Road, Amritsar-143601 (India)
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) Self attested copy of Memorandum of Association of Kwality Pharmaceutical Limited is submitted. (Pg. No. 87-91) (b) Self attested copy of **Certificate of Incorporation consequent upon conversion to Public Limited Company** (Corporate Identity No. U24232PB1983PLC005426) signed by Registar of companies Chandigarh dated 28.12.2015 is submitted where in it is stated that **Kwality Pharmaceutical Pvtl Ltd. which was originally Incorporated** on Fourth day of May Nineteen Hundred Eighty three under any previous company Law as Kwality Pharmaceuticals Pvt. Ltd., **the name of said company is this day changed to Kwality Pharmaceutical Limited**. (Pg. No. 92) (c) Self attested copy of list of signatories of Kwality Pharmaceutical Limited is submitted. (Pg. No. 93) (d) Self attested copy of Bidder information/Bidder Details as per Annexure V dated 16.08.2016 is submitted. (Page No. 94)
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) Self attested copy of Resolution of Board of Director of the company dated 12.08.2016 & attested by Satish Kumar Anand, Notary, Punjab, Govt. India, Amritsar is submitted wherein it is stated that Mr. Ajay Arora, Director of Company is here by Authorised to sign all the tender document. (Pg. No. 80)
3	List of item Quoted in prescribed format as Annexure III as per Clause 3 (o)	(a) Self attested copy of list of items quoted as Annexure III is submitted. (b) No. of quoted items- 17 only NIT S.No. 11 Cefixime Oral Suspension IP 100 mg/5l suspension, 30 ml NIT S.No. 15 Clindamyein Injection IP 150 mg/ml Injection, 2 ml NIT S.No. 19 Dicyclomine Hydrochloride Injection IP 10 mg/ml, 2ml NIT S.No. 21 Dopamine Injection IP 40 mg/ml, 5 ml. ampl. NIT S.No. 27 Heparin Sodium Injection IP 5000 units/ml, 5 ml. vial NIT S.No. 22 Drotaverine Hydrochloride Injection 40 mg/2 ml, 2 ml ampl. NIT S.No. 36 Ketamine Hydrochloride Injection IP 10 mg/ml, 10 ml. ampl. NIT S.No. 37 Lignocain Gel IP 2% w/v gel, 30 gm tube NIT S.No. 38 Lignocain Hydrochloride Injection IP 1% w/v, 30 ml vial NIT S.No. 39 Lorazepam Injection IP 2 mg/ml, 2 ml vial NIT S.No. 40 Magnesium Sulphate Injection IP 500 mg/ml, 5 ml ampl. NIT S.No. 45 Midazolam Injection IP 1 mg/ml, 5 ml vial NIT S.No. 56 Pralidoxine Chloride Injection IP 1 gm, 20 ml vial NIT S.No. 61 Rabeprazole Gastro Resistant tablets IP 20 mg NIT S.No. 74 Tranexamic Acid Injection IP 100 mg/ml, 5 ml ampl. NIT S.No. 75 Tranexamic Acid Tablets IP, 500 mg (Pack size is not mentioned in bid whereas in submitted list of item quoted it is mentioned as 10 X 10. NIT S.No. 108 Diclofenac Sodium Injection IP 25 mg/ml, 3 ml Amp. (Pg. No. 81-82)

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. • 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)	(a) Self attested copy of Licence to Manufacture for Sale or for distribution of drugs in Form 25 bearing License No. 1800-OSP, dated 15.02.2016 by Licensing Authority, Assistant Drug Controller, Punjab, Chandigarh of M/s Kwality Pharmaceuticals Limited, Village Nagkalan, Majitha Road, Amritsar is submitted in which it is stated that the Licence will be in force from 28.12.2015 to 27.12.2020. **Note: On the left bottom corner date of issue is also mentioned as 15.02.2015.** (Pg. No. 83-84) (b) Self attested copy of License to Manufacture for sale for for distrubution of Drugs in Form 28 bearing License No. 1804-B issued on 15.02.2016 by Licensing Authority, Assistant Drug Controller, Punjab, Chandigarh of M/s Kwality Pharmaceuticals Limited, Village Nagkalan, Majitha Road, Amritsar is submitted in which is stated that the Licence will be in force from 28.12.2015 to 27.12.2020. (Pg. No. 85-86) **Note: On the right top corner of Licence in Form 25 and Form 28 it is mentioned that Drug Manufacturing Licence No. 1800-OSP granted on 01.03.2006 renewed upto 28.02.2016 is reissued from 28.12.2015 due to change of constitution from private limited to limited company.** (Pg. No. 83 & 85) (c) Self attested copy of List of Items to be manufactured by M/s Kwality Pharmaceutical Pvt. Ltd. under Drug License No. 1800-OSP and 1804-B signed by LIcensing Authority, Assistant Drug Controller, Punjab, Chandigarh, dated 06.11.2012 is submitted where in the quoted product at NIT S.No. 36 is mentioned at S.No. 5 in the list of Items. **Note: (i) The specification of the product in NIT is IP where as in the list of Items to be manufactured the specification of said product is USP. (Pg. No. 39)** **(ii) The strenght in NIT is 10mg/ml where as the stenght in said product list 50gm/ml.** **iii) Ketamin Hydrochloride has been instituted under schedule X of Drug & Cosmetic Rules by GSR 724(E) dt-07-11-2013 w.e.f 07-11-2013 which requires licence to formulate for sale but the Licence in Form 35F is not submitted by Bidder Firm.** (d) Self attested copy of list of Non-Biological Drugs approved due to change of constitution w.e.f. 28.12.2015 from private limited to limited company under drug manufacturing license no. 1800-OSP and 1804-B M/s Kwality Pharmacueticals Ltd. signed by Licensing Authority, Assistant Drug Controller, Punjab, Chandigarh dated 15.02.2016 is submitted. (Pg. No. 40 to 55) where in (a) the quoted product at NIT S.No. 37 is mentioned at S.No. 12 of the list. **Note: The stength of the said product in NIT is 2% w/v where as the stength in the approved list of drug is 2% w/w. (Pg. No. 40) (b) The quoted product at NIT S.No. 39 is mentioned at S.No. 161 of the approval list.** **Note: The specification at NIT is IP where as specification of the said product in approved product list is BP/USP. (Pg. No. 42) (c) The quoted product at NIT S.No. 40 is mentioned at S.No. 164 of the approved list. Note: The specification as per NIT is IP where as the specification in approved list is BP/USP. (Pg. No. 43) (d) The quoted product at NIT S.No. 45 is mentioned at S.No. 182 of the approved list.** **Note: The specification as per NIT is IP where as the specificaiton in approved list is BP/USP. The strength as per NIT is 1 mg/ml where as in approved list strength is 5 mg/ml.** (Pg. No. 44) (e) The quoted product at NIT S.No. 56 is mentioned at S.No. 26 of approved list as Pralidoxime Chloride Injection IP. (Pg. No. 45) (f) The quoted product at NIT S.No. 61 is mentioned at S.No. 420 of approved list as Rabeprazole tablets IP. (Pg. No. 46) (g) The quoted product NIT S.No. 74 is mentioned at S.No. 271 of approval list. **Note: The specification as per NIT is IP where as in the approval list the specificatio of the drug is mentioned as BP.** (Pg. No. 47) (h) The quoted product NIT S.No. 75 is mentioned at S.No. 475 of approved list. **Note: (a) The specification as per NIT is IP where as the specification of drug in approval list is mentioned as BP. (b) Quoted product at NIT S.No. 75 is highlighted at S.No. 476 of approval list.** (Pg. No. 48) (i) The quoted product at NIT S.No. 108, 11, 15, 19, 22, 27 is mentioned as S.No. 108, 1, 6, 84, 103 and 11 of approval list. (Pg. No. 49-52 & 54-55) (j) The quoted product as NIT S.No. 21 is mentioned as S.No. 99 of approved list as Dopamine Hydrochloride Injection BP/USP. **Note: The specification of the said product as per NIT is IP where as in approved list the specification mentioned as BP/USP. Note: The specification of the said product as per NIT is IP where as in approved list the specificaiton mentioned as BP/USP. (Pg. No. 53)** (k) The quoted product at NIT S.No. 38 Lignocaine Hydrochloride Injection IP is highlighted at S.No. 155 but the name of the drug at S.No. 155 in approved list is mentioned as Lidocaine Hydrochloride Injection BP/USP. **Note: (1) Lignocaine Hydrochloride Injection BP/USP is menitoned at S.No. 158 but it is not highlighted as NIT S.No. 38 in approved list. (2) The strength as per NIT is 1% w/v where as in approved list the formulation mentioned as follows each ml contains: Lignocain Hydrochloride IP/BP/USP- 21.3 mg (Pg. No. 41)** **(e) Self attested copy of Market Standing/Performing Certificate No. Drugs/(5)Pb2016/7733, dated 15.07.2016 issued by Licensing Authority, Assistant Drug Controller, Punjab, Chandigarh is submitted where in it is stated that the above said firm is being manufacturing and marketing the following product since last three years under drug license no. 1800-OSP and 1804-B.** (Pg. No. 59-68 and 28-38)

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
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).	Self attested copy of Non-Conviction Certificate (No. Drugs(5)Pb2016/8062, dated 25.07.2016) issued by Licensing Authority, Assistant Drug Controller, Punjab, Chandigarh is submitted where in it is stated that the said firm (M/s Kwality Pharmaceutical Ltd.) has not been convicted during last five year by courts of law in this state under the provisions of Drugs & Cosmetic Act, 1940 & Rules made thereunder. (Pg. No. 70)
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).	Self attested copy of Certificate of Good Manufacturing practices (Certificate No. 1718/2016, dated 10.03.2016) issued by Licensing Authority, Assistant Drug Controller, Punjab, Chandigarh valid till 09.03.2018 along with forwarding letter submitted where in it is stated that the site (M/s Kwality Pharmaceutical Ltd.), Village Nakalan, Majitha Road, Amritsar indicated on the certificate complies with Good Manufacturing practices for the dosage form categories and activities in table I. (Pg. No. 56-57)

388

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).	Self attested copy of Manufacturing Capacity Certificate (No. Drug(4)Pb2014/17175, dated 27.06.2014) issued by Licensing Authority and State Drug Controller Authority is submitted where in installed manufacturing capacity of the firm per day (one shift of 8 hrs.) is mentioned. (Pg. No. 71-72)
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).	Self attested Notarised affidavit (with stamp) for Non-Blacklisting as per Annexure II of NIT is submitted. (Pg. No. 69)
11	EMD details (DD number/BG number and date with issuing bank) as per Clause 3(b) .	DD No "879595" `3,00,000/- Page No -96
12	Tender Fee Rs 10,000/- in form of DD as per Clause 3(a).	DD No "879591" `10,000/- Page No -97/-
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-2014-15 `629599849.76 Page No-75 FY-2013-14 `597614888.51 Page No-77 FY-2012-13 `619361491.97 Page No-73
14	Self attested copy of Income Tax Return for any three of last four consecutive Assessment years. As per Clause 3(m).	FY-2015-16 Page No-99 FY-2014-15 Page No-100 FY-2013-14 Page No-101

387

15	Self attested copy of PAN Card of the Bidder Company. As per Clause 3(p)	PAN No -AAACK6458M	Page No -103
16	Self attested copy of Certificate of valid Sales tax/VAT registration of the bidder company. As per Clause 3(q)	Reg No-03391061164	Page No -106
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).	Self attested Notarised affidavit (with stamp) regarding acceptance of tender conditions is submitted. (Pg. No. 98)	

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, in compliance of letter No 1146(15) Dt-05.11.2016 of Health Department, Govt of Bihar . Inspite, some inadvertent discrepencies could have been crept in. Humble request to all concerned to bring to notice in due time if any discrepencies is observed for rectification.