MINUTES OF TECHNICAL EVALUATION COMMITTEE MEETING OF TENDER NO. BMSIC/DRUGS/19-07 (RATE CONTRACT AND SUPPLY OF ALBENDAZOLE 400MG TABLET IP FOR DIFFERENT HEALTHCARE FACILITIES OF STATE OF BIHAR).

Date: 06th February 2020 **Venue: BMSICL Conference Hall.**

The **Technical Evaluation Committee Meeting of Tender No. BMSIC/DRUGS/19-07** was held on 06th February 2020 under the Chairmanship of Dr. Ashok Kumar, Director in Chief, Department of Health, GoB. The other committee members present in the meeting were:

1. Sh. Anil Kumar, Joint Secretary, Department of Health, GoB.
2. Sh. Khalid Arshad, AO, State Health Society.
3. Sh. Rajani Kant, CGM (Supply Chain), BMSICL.
4. Sh. Sunil Kumar Singh, GM (Procurement), BMSICL.
5. Dr. Biswaprakash Pradhan, DGM (Drugs), BMSICL.

2. The Details of the invited tender are as follows:

1. Tender Reference No. BMSIC/DRUGS/19-07.
2. Tender floated date- 25/07/2019.
3. Last date of submission of Online bids- 03/10/2019.
4. Tender Opening date- 04/10/2019.

3. Tender has been floated for 1 (One) drug i.e. Albendazole 400mg Tablet IP. It was found in online opening that following 15 (Fifteen) bidders had participated this tender.

1. Apple Formulation Pvt. Ltd
2. Associated Biotech
3. Cyano Pharma Pvt. Ltd.
4. Healthy Life Pharma Pvt. Ltd.
5. Jackson Laboratories Pvt Ltd.
6. Modern Laboratories.
7. Nestor Pharmaceuticals Ltd.
8. Omega Biotech Ltd.
9. Ravian Life science Pvt. Ltd.
10. Windlas Biotech Pvt. Ltd.
11. Ridley Life Science Pvt. Ltd.
12. Shine Pharmaceuticals Ltd.
13. Synmedic Laboratories.
14. Healer's Lab
15. Vivimed Labs Ltd.

4. It was therefore unanimously decided in tender opening committee meeting dated 04.10.2019 to recommend for technical evaluation of all received 15 bids.

5. The Preliminary Evaluation of technical bids of the above-mentioned bidding firms was done by the assigned team including Drug Inspectors deputed at BMSICL. Evaluation sheets were published on the website of BMSICL and Claims/Objections/Clarification were invited vide notice no. 4532 dated 04.11.2019.

6. After comparison of the clarification received from the bidders in the light of that notice published on website vide notice no. 4532 dated 04.11.2019 and close examination of the

documents submitted by the bidding firms, the firm wise technical evaluation findings were recorded by the TEC in its meeting dated 08.11.2019 as follows:

Sl. No.	Name of the Firm	Qualified/ Disqualified	Remarks
1	Apple Formulation Pvt. Ltd	Qualified	OK
2	Associated Biotech	**Decision Pending**	**Minimum three years old valid Manufacturing license & Valid Pollution Control Clearance Certificate needs to be verified during factory inspection.**
3	Cyano Pharma Pvt. Ltd.	**Decision Pending**	**Minimum three years old valid Manufacturing license needs to be verified during factory inspection.**
4	Healthy Life Pharma Pvt. Ltd	Qualified	OK
5	Jackson Laboratories Pvt Ltd.	Qualified	OK
6	Modern Laboratories	Qualified	OK
7	Nestor Pharmaceuticals Ltd.	Qualified	OK
8	Omega Biotech Ltd.	Qualified	OK
9	Ravian Life science Pvt. Ltd.	**Decision Pending**	**Affidavit (with stamp) regarding acceptance of tender condition needs to be verified during factory inspection.**
10	Windlas Biotech Pvt. Ltd.	Qualified	OK
11	Ridley Life Science Pvt. Ltd.	**Decision Pending**	**Minimum three years old valid Manufacturing license needs to be verified during factory inspection.**
12	Shine Pharmaceuticals Ltd.	Qualified	OK
13	Synmedic Laboratories	**Decision Pending**	**Minimum three years old valid Manufacturing license & Valid Pollution Control Clearance Certificate needs to be verified during factory inspection.**
14	Healer's Lab	**Decision Pending**	**Power of Attorney or Resolution of Board & Valid Pollution Control Clearance Certificate needs to be verified during factory inspection.**

15	Vivimed Labs Ltd.	**Decision Pending**	**Minimum three years old valid Manufacturing license needs to be verified during factory inspection.**

7. The manufacturing units of Modern Laboratoies, Shine Pharmaceuticals Ltd. & Windlas Biotech Pvt. Ltd. have been inspected within a year. It was unanimously recommended in last TEC meeting dated 08.11.2019 to carry out the factory inspection of the firms i.e., Apple Formulation Pvt. Ltd., Associated Biotech, Cyano Pharma Pvt. Ltd., Healer's Lab, Healthy Life Pharma Pvt. Ltd, Jackson Laboratories Pvt Ltd., Nestor Pharmaceuticals Ltd, Omega Biotech Ltd., Ravian Life science Pvt. Ltd., Ridley Life Science Pvt. Ltd., Synmedic Laboratories, Healer's Lab, Vivimed Labs Ltd. which are technically qualified as well as of those whose technical qualification status were depended upon factory inspection.

8. After perusal of the Factory Inspection report, the drug wise technical evaluation findings by TEC in its meeting dated 28.11.19 were recorded as follows:

Sl. No.	Name of the Firm	Technical bid Evaluation status before factory inspection	Recommendation of the TEC before Factory Inspection	Remarks of the Inspection team assigned for factory inspection	Recommendation of the TEC after Factory Inspection
1	Apple Formulation Pvt. Ltd	Qualified	OK	All drug manufacturing section are found as per schedule 'M' except oral liquid section due to unhygienic condition in filling area.	Qualified for Albendazole Tablet 400mg
2	Associated Biotech	**Decision Pending**	**Minimum three years old valid Manufacturing license & Valid Pollution Control Clearance Certificate needs to be verified during factory inspection.**	The company complies the parameters of NIT.	Qualified
3	Cyano Pharma Pvt. Ltd.	**Decision Pending**	**Minimum three years old valid Manufacturing license needs to be verified during factory inspection.**	The Manufacturing unit is technically fit for further tendering process.	Qualified
4	Healthy Life Pharma Pvt. Ltd	Qualified	OK	The Manufacturing unit is technically fit for further tendering process.	Qualified
5	Jackson	Qualified	OK	The company complies the	Qualified

	Laboratories Pvt Ltd.			parameters of NIT.	
6	Modern Laboratories	Qualified	OK	Already inspected earlier & found technically qualified.	Qualified
7	Nestor Pharmaceuticals Ltd.	Qualified	OK	All facilities are found as per schedule 'M'.	Qualified
8	Omega Biotech Ltd.	Qualified	OK	**All drug manufacturing section are in very unhygienic condition (Not as per Schedule M), the manufacturing unit (Building, Machine & equipment) is under renovation, reconstruction & under maintenance)**	**Decision Pending**
9	Ravian Life science Pvt. Ltd.	**Decision Pending**	**Affidavit (with stamp)regarding acceptance of tender condition needs to be verified during factory inspection.**	All facilities are found as per revised schedule 'M'.	Qualified
10	Windlas Biotech Pvt. Ltd.	Qualified	OK	Already inspected earlier & found technically qualified.	Qualified
11	Ridley Life Science Pvt. Ltd.	**Decision Pending**	**Minimum three years old valid Manufacturing license & needs to be verified during factory inspection.**	The company complies the parameters of NIT.	Qualified
12	Shine Pharmaceuticals Ltd.	Qualified	OK	Already inspected earlier & found technically qualified.	Qualified
13	Synmedic Laboratories	**Decision Pending**	**Minimum three years old valid Manufacturing license & Valid Pollution Control Clearance Certificate needs to be verified during factory inspection.**	All facilities are found as per revised schedule 'M'.	Qualified
14	Healer's Lab	**Decision Pending**	**Power of Attorney or Resolution of**	The company complies the parameters of NIT.	Qualified

			Board & Valid Pollution Control Clearance Certificate needs to be verified during factory inspection.		
15	Vivimed Labs Ltd.	**Decision Pending**	**Minimum three years old valid Manufacturing license needs to be verified during factory inspection.**	The Manufacturing unit is technically fit for further tendering process.	Qualified

9. It was therefore unanimously decided in last TEC meeting dated 28.11.19 to look into the issue of M/s Apple Formulation Pvt. Ltd & M/s Omega Biotech Ltd. afresh in connection with the Factory Inspection/ Physical verification report of Drug Inspectors and recommended for uploading the minutes in BMSICL web portal for clarification and objection if any.

10. After uploading the minutes of the TEC meeting dated 28.11.2019 on the website of BMSICL a letter was received from the firm M/s Omega Biotech Ltd, regarding the technical evaluation status after factory inspection. The **Claim/ Objection has been recorded in the following table:**

S.N.	Name of the Claimant/ Objector	Details of the Claim/ Objection	Supporting documents if any by the claimant
1	M/s Omega Biotech Ltd	We possess the valid manufacturing license, GMP Certificates as per revised Scheduled -M valid from 16/01/2019 to 15/01/2022 and GLP Certificate valid from 16/01/2019 to 15/01/2022 and our Company is certified ISO 9001:2015 valid till 31/12/2020. Copies of these certificate are enclosed. We also follow the GMP norms, Possess the necessary facilities for the production and proper procedures for control of all activities to ensure proper quality of the products during their shelf life and we maintain all documents Batch Production Record etc. and adopt proper procedures and maintain proper documents. Further we inform you that we are a regular supplier and supplied many drugs from the last few years and their rate contract no. BMSIC/40020/052017/4074 dtd. 06.03.2017 and BMSIC/40025/12-2016/3205 dtd. 26/02/2016. Especially we had supplied about 14 crore Albendazole Tablet 400 mg to you for the period	Yes (24 pages) 1) GLP Certificate 2) GMP Certificate, 3) ISO Certificate 4) Letter of Intent to M/s Omega Biotech Ltd against tender no. BMSIC/DRUGS /15-04 dated 24.08.15. 5) Letter of Intent to M/s Omega Biotech Ltd against tender no. BMSIC/DRUGS/15-05 dated 06.03.17. 6) Letter no. 29695 dated 27.08.2011 of SHS Bihar (Rate contract for drug

		from 2017 to 2018 and also, we are the past supplier of Bihar State Health Society, Patna from 2009 to 2015. Sir your Inspection team inspected our factory premises on dated 14/11/2019 and our factory was maintaining everything as per our certifications. However, they demanded money from us. In view of this we are filing this complaint against them and request your goodself to take necessary action if they try to malign our name.	supply in 38 districts of Bihar (Drug Round- VIII)).

11. After scrutiny of the claim/ objection received along with the supporting documents therein submitted by the bidder M/s Omega Biotech Ltd. the TEC in its last meeting dated 05.12.2019 unanimously recommended for following action:
I) To send the complaint petition to the Principal Secretary, Health Department for enquiry and onwards action against the concerned Drug Inspectors through the Managing Director, BMSICL.
II) To re-inspect the manufacturing unit of M/s Omega Biotech Ltd. & M/s Apple Formulation Pvt. Ltd by another team of Drug Inspectors headed by at least one Assistant Drug Controller.
III) BMSICL will take a call on the issue only after the receipt of revised inspection report.

12. Accordingly, the following action has been taken by BMSICL: -

I) The complaint petition of the firm M/s Omega Biotech Limited, received against the team of Drug Inspectors those inspected the firm M/s Omega Biotech Ltd. has been forwarded to the Principal Secretary, Health Department vide letter no. BMSIC/10080/9-2019/5538 dated 17.12.2019 for enquiry and onward action.

II) Vide letter no. BMSIC/40010/52-2019/5428 dated 12.12.2019, the State Drug Controller was requested for nominating a team of Drug Inspectors headed by a senior officer not less than the rank of Assistant Drug Controller of the Drug Control Department for the reinspection (with videography of the reinspection activity) of the manufacturing premises of M/s Omega Biotech Limited & M/s Apple Formulation Pvt. Limited.

13. Accordingly, vide Health Department's letter no. 1705 (15) dated 18.12.19 a three member team was constituted by the Drug Control section of the Health Department, consisting of Sri Mahesh Ram (Assistant Drug Controller, Saharsa), Sri Sandeep Sah (Drug Inspector, Patna-10) & Sri Dhananjay Kumar (Drug Inspector, Muzzafarpur-05) who were entrusted with the re-inspection task along with videography of the same. The said inspection team was directed to submit a detailed report regarding their findings pertaining to the re-inspection of the manufacturing premises of M/s Omega Biotech Limited & M/s Apple Formulation Pvt. Limited.

14. The said re-inspection along with videography of the said activity of the manufacturing unit of M/s Apple Formulation Pvt Ltd situated at 208, Khasra No. 445, Kishanpur, Bhagawanpur, Roorkee Haridwar, Uttrakhand was conducted on 27.12.2019. and M/s Omega Biotech Ltd. situated at 7th Mile Stone, Dehradun Road, Roorkee, Distt. Haridwar, Uttarakhand was conducted on 28.12.2019 by the re-inspection team. The inspection team

has submitted the detailed re-inspection report to BMSICL along with the video recording of the re-inspection activity in compact disc, on 30.12.2019.

15. The Technical Evaluation Committee in its meeting dated 01-01-2020 examined the matter taking into consideration the following points: -

I) The detailed re-inspection report as submitted by the re-inspection team.
II) The detailed video recording of the re-inspection activity as submitted by the re-inspection team.
III) The detailed video recording of the re-inspection activity as submitted by M/s Omega Biotech Ltd.
IV) The complaint petition of M/s Omega Biotech Ltd., submitted to BMSICL on 30.12.2019.
V) The complaint petition of M/s Omega Biotech Ltd., submitted to Honourable Deputy Chief Minister, Bihar on 13.12.2019.

The concerned bidder-wise remarks of the re-inspection team are recorded in table- 1 and the claim/ objection of M/s Omega Biotech Ltd. is recorded in table- 2, given herein below: -

Table-1

Sl. No.	Name of the Firm	Remarks of the Inspection team assigned for re-inspection
1	Apple Formulation Pvt. Ltd.	जाँच टीम ने संस्थान के विभिन्न Sections का भौतिक जाँच किया तथा पाया कि किसी भी section जैसे– tablet section, capsule section, ointment/cream section तथा liquid section में unsatisfactory condition नही है तथा drugs and cosmetic act-1940 के विभिन्न पहलुओ का पालन किया जाता है।
2	Omega Biotech Ltd.	दिनांक 28/12/2019 को सरकार के संयुक्त सचिव, स्वा० विभाग, बिहार पटना के पत्रांक 1705 (15) स्वा० दिनांक 18/12/2019 के द्वारा औषधि नियंत्रक प्राशासन के तीन सदस्यीय टीम द्वारा जिला पदाधिकारी सह जिला मजिस्ट्रेट, हरिद्वार द्वारा दिये गये निदेश के आलोक में Joint Magistrate सह S.D.M. Roorkee के द्वारा प्रतिनियुक्त नायब तहसीलदार मंगलोर (N.T(M)) तथा S.H.O. Bhagwnapur Roorke से निर्देशित पुलिस पदाधिकारी की उपस्थिति में सम्पूर्ण जाँच प्रक्रिया का videography कराते हुये M/s Omega Biotech Ltd. का जाँच BMSICL, Patna द्वारा उपलब्ध कराये गये inspection format तथा निर्देशित बिन्दुओ पर किया गया, विवरणी निम्न प्रकार है। 1. संस्थान को प्रदत अनुज्ञाति संख्याः– 8/UA/SC/P/2004; FORM- 28, तथा 13/UA/2004- FORM- 25, Date of issue- 15/12/04. दिनांक 14/12/2024 तक के लिए Retension certificate issued by Drug Controlling & Licensing authority U.K. 2. सम्पूर्ण जाँच के दौरान Shri. Girish Chand Sharma, Q.C. manager अपने अन्य Technical staff के साथ present रहे तथा प्राधिकृत videography कराया गया। 3. जाँच के दौरान production area में कार्य कर रहे वैसे staff जो core area (Direct Contact to medicine) में कार्य कर रहे थे वे full uniform, यानी (सिर्फ apron पहने थे) नही पहने थे। 4. Capsule/ tablet/ oral liquid तथा external preparation production area का door automatic closed system के अनुसार नही पाया गया, जिससे humidity, temperature इत्यादी S.O.P के अनुसार maintain नही किया जा सकता है। 5. Tablet तथा oral liquid production area में open ventilation के साथ–साथ open exhaust fan पाया गया जो नियामानुकूल नही होना चाहिए। 6. Pressure differential system किसी भी section में नियामानुकूल नही पाया गया। 7. Dispensing Area में computer, table chair पाया गया।

		8. Production area में कतिपय installed instrument का status tag नही पाया गया। 9. Tablet/ Capsule/ External preparation production area का floor joint पाया गया तथा S.O.P. के अनुसार clean नहीं पाया गया। Oral liquid production area का floor smooth नही पाया गया, joint पाया गया, floor पर काफी cracks पाया गया, oral liquid section का maximum wall का area, floor का area तथा corner काफी गन्दा (unclean) पाया गया, जो नियमानुकूल नहीं है। 10. Primary packing store room में संधारित printed aluminum foil पर पूर्व में mfg. किये गये कतिपय औषधियों का M/d, B. No., E/d., stereo से printed/ mark किया हुआ पाया गया। 11. जाँच के दौरान tablet production area में पाया गया कि tablet की packing machine से strip tablet packing किया जा रहा है, संस्थान के technical staff के उपस्थिति में देखा गया की Diclogem tablets, composition: each uncoated tablet contain Diclofenac sod. I.P. 50 mg, Paracetamol I.P. 325 mg का packing किया जा रहा है जिस पर B. No. BT9399, M/d- 11/2019, E/d- 04/22, MRP- 19.00 per 10 tablets अंकित किया जा रहा है, ध्यान हो कि packing 28th December को किया जा रहा है, तथा M/d- 11/19, Nov-2019 mentioned किया जा रहा है। माँगे जाने पर Batch Production Report प्रस्तुत नहीं किया गया, तथा staff द्वारा गलती मानते हुए packing रूकवाया गया, साक्ष्य के रूप में videography देखा जा सकता है। तथा tablet का एक strip एवं secondary packing (cartoon/ box) संलग्न किया जा रहा है। 12. टीम द्वारा validation of equipment done से संबंधित document माँगे जाने पर प्रस्तुत नही किया गया, तथा बतलाया गया की report उपलब्ध नहीं है।

Table-2

Sl. No.	Details of the Claim/ Objection raised by M/s Omega Biotech Ltd.
1.	Referring to our complaint vide letter dated 19-11-2019 based on which Documents Verification and Factory Inspection Report submitted by the first team of Drug Inspectors was kept in abeyance and subsequently appointed another team (re-inspection team). Kindly refer Minutes of Technical Evaluation Committee Meeting held on 5th December, 2019 under the Chairmanship of Director in Chief, Department of Health, GOB. Having come to know about the presence of the inspecting team in the city we had contacted them on 21-12-2019 and they confirmed about their visit to our on 23-12-19 or 24-12-19 to conduct re-inspection as assigned to them. On both the days we kept our self-waiting but unfortunately, neither they visited the Factory nor had left any information or message in this regard. We also tried our best to contact them again but in vain. The matter was promptly brought to your kind notice vide our letter dated 24-12-19. However, on 28-12-2019 they had suddenly came with one Tahsildar and Local Police and stormed in to the Factory Premises appearing as such company has committed a serious crime leaving all the employees of the company confused and panic. The entire drama was planned and staged deliberately by the inspecting team and that too without any provocation for the reason best known to them. May be because of the disclosure of corrupt practices of their colleagues, who were part of earlier team, they were upset and had planned accordingly to take revenge and to punish the company. In the name of inspection entire area of the premise including working and **non-working area were video graphed.** The entire action of the inspecting team is highly condemnable and requires a thorough investigation and enquiry to prevent corrupt practices. However, in order to prevent any distortion of facts, we had also conducted parallel videography copy of which is being forwarded. That in this regard, it is pertinent to bring it to your kind notice that in mutual trust and understanding we allow the inspectors to visit inside the Factory for carrying out inspection to see the capacity of the plant and it's status in present scenario even knowing fully well that the local working areas assigned to them and notified are limited within the jurisdiction of Bihar and any exercise of acts and powers outside it's jurisdiction shall be held illegal. Powers, authority and jurisdiction are will defined in Section 1(3), Section 21, Section 22 and Rule 51 & Rule 52 in details as under for kind perusal. 1. That **Section 1 (3)** of the Drugs and Cosmetics Act 1940 – it shall come into force once; but Chapter III shall take effect only from such date as the Central Government may, by the notification in Official Gazette, appoint in this behalf and **chapter IV shall take effect in**

particular State only from such date as the State Government may, by like notification, appoint in this behalf.

2. **CHAPTER IV of the Act is concerned to manufacture, sale and distribution of Drugs and Cosmetics.**
3. **Section 21: Inspectors** – (i) the Central Government or State Government may, notification in Official Gazette, appoint such persons as he thinks fit, having the prescribed qualification, to be Inspectors of such areas as may be assigned to them by the Central Government or State Government, as the case may be.

(ii) The powers which may be exercised by an Inspector and the duties which may by performed by him, the drugs [classes of drugs and cosmetics or classes of chemicals] in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed shall be such as may be prescribed.
(iii) No person who has any financial interest [in the import, manufacture of drugs or cosmetics] shall be appointed to be an Inspector under this section.
(iv) Every Inspector shall be deemed to be a public servant within the meaning of Section 21 of the Indian Penal Code (45 of 1860) and shall be officially subordinate to such authority [having the prescribed qualifications], as the Government appointing him may specify in this regard.

4. **Section 22, Powers of Inspectors** – (1) Subject to the provisions of Section 23 and of any rules made by the Central Government in this behalf, an Inspector may, **the local limits of the area for which he is appointed- [(a) Inspect -**
5. **Rules 51:** Duties of Inspectors of premises licensed for sale- Subject to the instructions of the controlling authority, it shall be duty of an Inspector authorized to inspect premises licensed for sale of durgs (1) to inspect [not less than once a year] all establishments licensed for sale of the drugs **within the area assigned to him**; (2) to satisfy himself that the conditions of the licenses are being observed.
6. **Rule 52**; Duties of Inspector specially authorized to inspector specially authorized to inspect the manufacture of [drugs or cosmetics]- Subject to the instructions of the controlling authority it shall be duty of an Inspector authorized to inspect the manufacture of durgs (1) to inspect [not less than once a year], all the premises licensed for manufacture of [drugs and cosmetics] **within the area allotted to him** to satisfy himself that the conditions of the license and provisions of the Act and Rules there under are being observed.

Taking into consideration the aforesaid facts and the provisions of the Act it is clear beyond doubt that the entire exercise right from appointment of a team consisting of Drug Inspectors and ADC for carrying out Factory Inspection situated out side of the state is entirely illegal and hence, any report submitted by them be rejected if taken from closed unit. The authorization and appointment letter bearing no. 1705 (15) dated 18-12-2019 issued by the Joint Secretary, Health, Government of Bihar also does not conform the provisions of the Acts and hence, required to be withdrawn with immediate effect.

That the District Officer cum District Magistrate, Haridwar, Uttarakhand was also mislead and misinformed resulted to act there by without examining the legality and jurisdiction of state constitution under Chapter IV of the Drug Act. We are living in a society where law of the land prevails. In public procurement in order to maintain fairness and transparency; Finance Department, the Government of Bihar thorough Bihar Finance (Amendment Bull) Rules, 2005 has also emphasized that "The bidding documents should indicate clearly that the resultant contract will be interpreted under **Indian Law**", kindly refer Rule 131R 9 Sub Clause (IV).

That the matter of serious enough. It is an open demonstration of blunted misuse of powers and authorities. In past also in course of Factory Inspection involvement of certain Inspectors in corrupt practices were reported but unfortunately, instead of taking corrective action matters were suppressed. Hope, in order to maintain fairness and transparency in Public Procurement immediate corrective action shall be initiated by the Corporation and the Department. However in this regard, it may kindly be noted that in future Drug Inspectors without having notifications as regard of local areas

	assigned to them respectively as provisioned under the Chapter IV of the Drugs and Cosmetics Act, 1940, shall not be allowed inside the manufacturing area unless having proper permission form the local drug administration.
2.	We possess the valid manufacturing license, GMP Certificates as per revised Scheduled -M valid from 16/01/2019 to 15/01/2022 and GLP Certificate valid from 16/01/2019 to 15/01/2022 and our Company is certified ISO 9001:2015 valid till 31/12/2020. Copies of these certificate are enclosed. We also follow the GMP norms, Possess the necessary facilities for the production and proper procedures for control of all activities to ensure proper quality of the products during their shelf life and we maintain all documents Batch Production Record etc. and adopt proper procedures and maintain proper documents. Further we inform you that we are a regular supplier and supplied many drugs from the last few years and their rate contract no. BMSIC/40020/052017/4074 dtd. 06.03.2017 and BMSIC/40025/12-2016/3205 dtd. 26/02/2016. Especially we had supplied about 14 crore Albendazole Tablet 400 mg to you for the period from 2017 to 2018 and also, we are the past supplier of Bihar State Health Society, Patna from 2009 to 2015. Sir your Inspection team inspected our factory premises on dated 14/11/2019 and our factory was maintaining everything as per our certifications. However, they demanded money from us. In view of this we are filing this complaint against them and request your good self to take necessary action if they try to malign our name.

16. The TEC in its last meeting dated 01.01.2020 examined the reports of the re-inspection team in detail, but due to the time constraint, the TEC could not go through all the video recordings submitted by the re-inspection team & M/s Omega Biotech Ltd. as well. Hence it was unanimously decided by Technical Evaluation Committee to sit again on 16.01.2020 at 15:00 Hrs. to examine the matter regarding technical qualification status of the concerned firm M/s Apple Formulation Pvt. Ltd. and M/s Omega Biotech Ltd.

17. Accordingly, the Technical Evaluation Committee meeting was conducted on 16.01.2020 in continuation of the previous Technical Evaluation Committee meeting held on 01.01.2020. After perusal of the Factory Inspection report, Factory re-inspection report, the video recordings submitted by re-inspection team & M/s Omega Biotech Ltd. and the claims/ objections raised by the M/s Omega Biotech Ltd., TEC in its meeting dated- 16.01.2020, observed that: -

i) First physical verification of M/s Omega Ltd. was carried out on 14.11.2019. It was reported that drug Manufacturing Section is unhygienic and the manufacturing unit is under renovation, reconstruction and under maintenance. Even at that time the company possessed GMP and GLP Certification and all other requisite Licenses.

ii) The firm M/s Omega Ltd. was re-inspected on 28.12.2019 after which the re-inspection team reported that woody furniture and close door system was not found in the company's manufacturing premises. The re-inspection team elaborated minute details of the irregularities in the manufacturing practices of the bidder M/s Omega Biotech Ltd., which was substantiated by the video-recording of the manufacturing premises of M/s Omega Biotech Limited. The videography submitted by the bidder corroborate the factual evidence as outlined by the re-inspection team in their report as contained in table – 1. Mal packaging of drugs has been pointed out by the re-inspection team which is a serious concern for which corrective measures are required to be taken. So far hygiene and other physical conditions of the said firm are concerned, these are the prerequisites for the License Issuing Authorities.

iii) The video-recording of the manufacturing premises submitted by the bidder M/s Omega Biotech Limited bears resemblance with that submitted by the re-inspection team and proves the deficiencies pointed out by the re-inspection team. The TEC during the evaluation process observed that the bidder firm M/s Omega Biotech Limited possess GMP, GLP certificates and all other requisite Licenses, which has been issued by the State Drug Licensing Authority, Uttarakhand.

18. The TEC in its meeting dated 16.01.2020, unanimously decided that, since the bidder firm M/s Omega Biotech Limited possess GMP, GLP certificates and all other requisite Licenses, hence before coming to any final conclusion regarding disqualification of the bidder firm M/s Omega Biotech Limited, it would be proper to take the opinion of the State Drug Licensing Authority, Uttarakhand.

19. It was therefore unanimously recommended by the Technical Evaluation Committee in its meeting dated 16.01.2020 to intimate all the above findings along with all documents submitted by the inspection team and the re-inspection team, video recording of the re-inspection activity as submitted by the re-inspection team as well as by the bidder firm M/s Omega Biotech Ltd. to the concerned Drug Controlling and Licensing Authority of Uttarakhand for inviting their opinion in this regard.

20. By considering the report of the re-inspection team, the Technical Evaluation Committee in its meeting dated 16.01.2020 further recommended that M/s Apple Formulation Pvt. Ltd. as technically Qualified for the drug Albendazole Tablet 400mg vide this tender no. BMSIC/DRUGS/19-07.

21. Vide BMSICL office order no.- BMSIC/50040/15-2017/6765, dated- 04.02.2020, the bidder firm M/s Omega Biotech Limited is blacklisted for a period of two (02) years form the date of the issue of this order. Accordingly, this TEC meeting is scheduled today for drawing a conclusion regarding the technical evaluation status of the bidder firm M/s Omega Biotech Limited.

22. Non-Blacklisting of the firm and its quoted product is the Minimum Eligibility criteria for bidding/ participating in any tender floated by BMSICL. In this regard, the clause no.- 3 (n) of the bid document states that, "The tenderer should give 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 date of submission of the tender) by Central Government / Central Government agencies/any state government or any of the state government agencies / or any Drug procurement agencies or by BMSICL as per Annexure-II".

23. As the firm has been blacklisted by BMSICL the Technical Evaluation Committee in its today's meeting unanimously recommended for not considering the bidder firm M/s Omega Biotech Limited for further tender process.

24. It was therefore unanimously decided by the TEC in today's meeting to recommend for opening of the financial bids of M/s Apple Formulation Pvt. Ltd, M/s Associated Biotech, M/s Cyano Pharma Pvt. Ltd., M/s Healthy Life Pharma Pvt. Ltd., M/s Jackson Laboratories Pvt Ltd., M/s Modern Laboratories, M/s Nestor Pharmaceuticals Ltd., M/s Ravian Life Science Pvt. Ltd., M/s Windlas Biotech Pvt. Ltd., M/s Ridley Life Science Pvt. Ltd., M/s Shine Pharmaceuticals Ltd., M/s Symedic Laboratories, M/s Healer's Lab and

M/s Vivimed Labs Ltd. those are found technically qualified for the drug Albendazole Tablet 400mg vide this tender no. BMSIC/DRUGS/19-07.

25. The meeting was thus concluded with a vote of thanks.

Sd/-
(Dr. Biswaprakash Pradhan)
DGM (Drugs), BMSICL, Patna.

Sd/-
(Sunil Kumar Singh)
GM(Procurement), BMSICL, Patna

Sd/-
(Rajani Kant)
CGM (Supply Chain), BMSICL, Patna.

Sd/-
(Khalid Arshad)
Administrative Officer, SHSB.

Sd/-
(Anil Kumar)
Joint Secretary, Health Dept. Govt. of Bihar.

Sd/-
(Dr. Ashok Kumar)
Director in Chief, Health Dept.
Govt. of Bihar.