File No- BMSIC/50040/15-2017/ **Date:- /02/2020**

Order

M/s Omega Biotech Ltd, 7th Mile Stone, Saliyar, Dehradun Road,Roorkee-247667, Uttarakhand was issued the Purchase Orders bearing no- BMSIC/40020/05-2017/1664 dated 11-08-2017 & BMSIC/40020/05-2017/4061 dated 13-01-2018 for the supply of 1000000 (Ten lakh Tablets) & 1300000 (Thirteen lakh Tablets) units of Cefuroxime Axetil Tablets IP 125 mg respectively. The firm supplied the said drug in 03 batches bearing batch no- ET70336, LT70791 & LT70790 which were declared as **"Not of Standard Quality" (NSQ)** by different BMSICL empanelled laboratories. Out of said 03 batches, 02 batches are found to be spurious by CDL Kolkata. The details of batches of quality check report of various batches of said drug is given herein below: -

S.No	Name of the drug	Batch No and date of receipt.	BMSICL Empanelled Laboratory Report Status	CDL Laboratory Report Status	Reason for declaring NSQ by CDL	Show Cause Notice Issued
1	Cefuroxime Axetil Tablets IP 125 mg	ET70336 received on 29-11-2017.	Found NSQ by Ozone Pharmaceuticals Ltd on 19-12-2017.	CDL Report is awaited.	--	Vide show cause notice no- BMSIC/50040/15-2017/4163 dated 19-01-2018, BMSIC/50040/15-2017/2344 dated 23-08-2018 & BMSIC/50040/15-2017/5018 dated 26-11-2019.
		LT70790 received on 13-04-2018, 03-04-2018 & 11-04-2018.	Found NSQ by Devansh Testing & Research Laboratory on 28-04-2018. Found NSQ by Interstellar testing Centre on 12-05-2018.	Found Spurious on 11-10-2019. (NSQ)	**The sample does not confirm to I.P. with respect to Identification and Assay of Cefuroxime Axetil.** **The sample is deemed to be spurious as per sec 17B of the Drugs and Cosmetics Act and Rules 1945.**	Vide show cause notice no- BMSIC/50040/15-2017/716 dated 24-05-2018 & BMSIC/50040/15-2017/2344 dated 23-08-2018 & BMSIC/50040/15-2017/5018 dated 26-11-2019
		LT70791 received on 11-04-2018, & 13-04-2018.	Found NSQ by Devansh Testing & Research Laboratory on 11-05-2018.	Found Spurious on 11-10-2019. (NSQ)		Vide show cause notice no -BMSIC/50040/15-2017/2344 dated 23-08-2018 & BMSIC/50040/15-2017/5018 dated 26-11-2019.
		LT70791	Found NSQ by Ozone Pharmaceuticals Ltd on 07-05-2018.			

2. It seems pertinent to quote the relevant provisions of the bid document pertaining to the above said tender:-

(i) Clause 24 (e) of the referred Bid Document states that, "*The drugs shall be of standard quality throughout the shelf life period of the item. Samples can be drawn for quality testing periodically throughout the shelf life period. If the sample is declared to be "NOT OF STANDARD QUALITY" or spurious or adulterated or misbranded, such batch/ batches will be deemed to be rejected goods and action will be taken as per tender clause.*"

(ii) Clause 24 (f) of the referred Bid Document states that, *"If the product / sample fails in quality test, every failed batch shall be taken back by the supplier at their own cost and BMSICL shall not be responsible for any damage during this period."*

(iii) Clause 27 B (3) of the referred Bid Document states that, *"If 3 batches of a particular item supplied by the supplier is reported to be failing in ASSAY content (above 50% but below prescribed limit) and/or other parameters, then the particular item of the firm shall be blacklisted for minimum of two years besides forfeiture of Security Deposit of that particular product(s)".*

(iv) Clause 27 B (5) of the referred Bid Document states that, "*If a single batch of any product(s) supplied by the company/firm declared as Adulterated/spurious/ Misbranded by the Government Authorities during the shelf life of the product supplied irrespective of tender period, the company/firm shall be blacklisted for a period of 2* ***years from the date of intimation & forfeiture of security deposit."***

3. In view of the test reports obtained from various BMSICL empanelled NABL Accredited Laboratories and Central Drug Laboratory (CDL), Kolkata four (04) show cause Notices i.e, Show cause notice no- **BMSIC/50040/15-2017/4163 dated 19-01-2018, BMSIC/50040/15-2017/716 dated 24-05-2018, BMSIC/50040/15-2017/2344 dated 23-08-2018 & BMSIC/50040/15-2017/5018 dated 26-11-2019** were issued to M/s. Omega Biotech Ltd (the details of the show cause notices issued against each batch are mentioned in the above table), seeking explanation within 7 days of issue of each notice. In the said notices the company was asked to show cause as to why BMSICL should not initiate necessary action against the said firm in accordance with the terms outlined in Tender Clause 24(f), Clause 27 B (3) Clause 27 B (5) contained in bid reference no- BMSIC/DRUGS/15-05.

4. The first show cause notice bearing no. **BMSIC/50040/15-2017/4163 dated 19-01-2018** referred to the batch no. **ET70336** of the drug **Cefuroxime Axetil Tablets IP 125 mg** which was found to be NSQ was served on the firm M/s. Omega Biotech Ltd. The quality check report of the BMSICL empanelled laboratory was also accordingly attached along with the show cause notice. In the mean time on failure of the batch no. **ET70336** of the above said drug, State Drug Controller (SDC), Bihar was requested to get the sample of the said batch collected at his end for qualitative analysis of the same by a Government Laboratory vide letter no.- BMSIC/50040/15-2017/3835, dated 02-01-2018.

5. In response to the show cause notice no- BMSIC/50040/15-2017/4163 dated 19-01-2018, the firm M/s. Omega Biotech Ltd vide its letter dated **20-01-2018 (bearing reference no.- OB/Bihar/Cef/01)** informed that, "We have received your above mentioned email regarding failed batch of Cefuroxime Axetil Tablets IP 125 mg. In this regard we hereby inform you that we have

ready to withdraw the product at our own cost from the drug warehouses. Our representative will collect the material from the Drug Warehouses."

6. In the meantime another batch having no. **LT70790** of the said drug **Cefuroxime Axetil Tablets IP 125 mg** of the said firm M/s. Omega Biotech Ltd was also found to be NSQ by another empanelled NABL accredited lab of BMSICL. Hence the firm was served with another show cause notice bearing no. **BMSIC/50040/15-2017/716 dated 24-05-2018.** State Drug Controller (SDC), Bihar was requested vide mail dated 16-05-2018 (for batch no. **LT70790** and **LT70791**) and vide letter bearing no.- BMSIC/50040/15-2017/735, dated 24-05-2018 (for batch no. **LT70790**) to get the sample collected at his end for qualitative analysis of the same by a Government Laboratory.

7. In response to the said show cause notice no- BMSIC/50040/15-2017/716 dated 24-05-2018, the firm M/s. Omega Biotech Ltd vide its letters dated **31-05-2018 (bearing reference no.- OB/Bihar/2018/01) & 25-06-2018 (bearing reference no.- OB/Bihar/2018/01)** informed that, "We have received your above mentioned email regarding failed batch of Cefuroxime Axetil Tablets IP 125 mg having batch no- LT70790, in this regard we hereby informed you that we have ready to withdraw the product at our own cost from the drug warehouses. Our representative will be collecting the material from the Drug Warehouses."

8. **Again vide letter dated 24-07-2018,** the firm M/s. Omega Biotech Ltd informed that, " After that we get information from your office we immediately checked the control sample of subject batch no. drug in our lab as well as another three Govt. Approved NABL Certified Labs and found that subject batch no. drug is of standard Quality of IP in respect of Dissolution Test as well as other tests. Photo copy of the COA of own Lab and Govt./NABL Approved Labs enclosed for your ready reference. That Cefuroxime Axetil API/tablets is very sensitive to heat light and moisture, if the subject item do not store as prescribed on the strip/carton then the drug may be effected. So you hereby advise store the subject item as prescribed on the strip/carton. So in view of the above we disagree with COA of your empanelled lab and challenge the same under section 25 (iii) and (iv) of Drugs and Cosmetic Act 1940 and Rules made there under and requested you considered the subject batch no. drug is of standard quality IP."

9. It was further found that apart from the above said two failed batches, a third batch bearing batch no. **LT70791** of the said drug **Cefuroxime Axetil Tablets IP 125 mg** manufacture and supplied by the said firm M/s. Omega Biotech Ltd was also declared NSQ by two different BMSICL empanelled lab following which the firm was again served with a third show cause notice bearing no. **BMSIC/50040/15-2017/2344 dated 23-08-2018.**

10. In response to the show cause notice no- BMSIC/50040/15-2017/2344 dated 23-08-2018, the firm M/s. Omega Biotech Ltd vide its letter dated **29-08-2018 (bearing ref no- OB/Bihar/2018/05)** informed that "1. That two batch nos. LT70790 and ET70336 of subject item we have withdrawal and third batch no. LT70790 we have challenged vide reference letter dated 24-07-2018. 2. That we had manufactured above batches as per GMP norms and tested the same in our Own Lab as well as outside NABL approved lab and found the subject batch nos. item of standard quality as per IP 2014 and after that dispatched the same various Hospitals of Bihar Govt. as per order. 3. The batch no. ET70336 your empanelled lab failed in Discerption and observed slightly few grayish spots on few tablets only which is minor fault. 4. That batch no. LT70790 & LT70791 your empanelled lab failed the sample in Dissolution test but in the test report they have not tested the above batch no. item Dissolution test upto S3 stage as per IP 2014 Norms for

Dissolution test. 5. That the Dissolution tests and Description both are minor test and comes under category of B & C of Not of Standard quality of Drugs respectively as per Drugs and Cosmetics 1940 & Rules made there under and which is may be possible due to storage condition of the Drug and prescribed on the strips/ carton. So, in this view we requested you please do not Blacklisted our firm above for item because all the batches of subject item we have withdrawal from your hospitals and one batch LT70791 we have challenged the COA of your Empanelled Lab."

11. **Again vide letter dated 03-12-2018,** the firm, M/s. Omega Biotech Ltd informed that, "We disagree with COA of your empanelled lab and challenge the same under section 25 (III) and (IV) of Drugs and Cosmetic Act 1940 and Rules made there under and requested you consider the subject batch no. drug is of standard quality IP."

12. As evident from the facts stated in the aforesaid paragraphs, it is clear that after the failure of each batch of the drug **Cefuroxime Axetil Tablets IP 125 mg** as analysed by the BMSICL empanelled laboratories, the State Drug Controller, Bihar at the request of BMSICL got a sample of each batch of all the three impugned batches separately collected by his team and sent the said samples to the Government Laboratory for its qualitative analysis.

13. Analysis reports of two batches (batch no. **LT70791** and **LT70790** of the drug **Cefuroxime Axetil Tablets IP 125 mg)** prepared by the Central Drugs Laboratory (CDL), Kolkata was received by BMSICL through the State Drug Authorities. The analysis report of both the batches of the said drug revealed that CDL, Kolkata has declared both the batches to be **'Spurious'.** In view of the above fact the reply of the firm was thus not found to be tenable either in fact or law.

14. Hence the firm M/s. Omega Biotech Ltd was served with a fourth show cause notice bearing no. **BMSIC/50040/15-2017/5018 dated 26-11-2019** in which the reports as received from the CDL, Kolkata were attached. The said firm was asked to show cause as to why the provision contained in clause 27 B (5) should not be invoked against it. Clause 27 B (5) as mentioned in the above said paragraph no. 2(iv) was also quoted in the said show cause notice served on the firm M/s. Omega Biotech Ltd.

15. In response to the show cause notice no- BMSIC/50040/15-2017/5018 dated 26-11-2019, the firm M/s. Omega Biotech Ltd vide its letter dated **05-12-2019,** informed that, "We are not satisfied with the finding of Govt. analyst reports, bearing report no- 8-2/2019/SS/BR-47/2490 dated 11-10-2019 and report no- 8-2/2019/SS/BR-46/2489 dated 11-10-2019 on Form-13. We do not accept the result of Govt. analyst report on Form-13. So, we have reserved our right to challenge the same as when as required. The report of re-test or re-analysis on Form- 2 form appellate lab CDL, Kolkata is still awaited. So, in the interest of justice it essential to wait the report of re-test or re-analysis from CDL, Kolkata, in this circumstance no any coercive action against us should not be taken."

16. **Again vide letter dated 09-12-2019,** the firm M/s. Omega Biotech Ltd reiterated all the points mentioned in its earlier replies and also informed that, "It would be more relevant and appropriate to invite your attention to the notification no. Sl. No. 6076 (F92) of Finance department Govt. of Bihar read as the Bihar Finance (Amendment Bill) Rules, 2005 under which in Rule 131R 9 (Transparency, completion, fairness & elimination of arbitrariness in the procurement process, sub clause (iv) has spelled out clearly that "The bidding documents should indicate clearly that the resultant contract will be interpreted under Indian Law." Therefore, it is earnestly requested that

necessary precaution is required to be maintained while proceeding further pre-maturely in order to punish the company and that too, without taking into account the Indian law in question. Otherwise also as directed both failed batches of drugs were withdrawn immediately and had been replaced fully by new batches. Taking into consideration the aforesaid facts as well as the legal position we hope, matter will be taken in right prospective and your good self will be kind enough to defer with any punitive action in lieu to the provision under clause 27 B(f) of the tender, in case being proposed or contemplated against the company."

17. **Again vide letter dated 16-01-2020,** the firm M/s. Omega Biotech Ltd further informed that, "Referring to the subject this is to inform that we were in receipt of another notice under reference form the drug inspectors, Muzaffarpur against which we had challenged and notified our intension to controvert the test report of Govt. analyst vide our letter 03-01-2020 within 28 days from the date of receipt of test report as provisioned under section 25 (3) of the Drug And Cosmetics Acts 1945 making test reports completely non operative with immediate effect unless it is retested in Central Drug Laboratories (CDL), Kolkata. While submitting our reply to corporation's notice our vide letter 09-12-2019 we had explained the legal positions and its application in detailed including the observation made be the hon'ble Supreme Court of India in the matter of Amrey Pharmaceuticals vs. State of Rajasthan 2001 drug case 186. Therefore, at this point of time when the matter is legally disputed and the subjudiced initiation of any proceeding or action against the company by using the test reports of Govt. analyst which have automatically lost its evidential value immediately after company's notification w.e.f. 03-01-2020, shall be in proper and considered to be illegal. Therefore we would request your good self-look into mater reasonably taking into account the entire facts and its legality matter is required to be deferred till the final outcome of subjudiced matter."

18. As evident from the analysis report status given by three different BMSICL empanelled NABL Accredited Laboratories, it is clear that all the three batches of the said drug Cefuroxime Axetil Tablet IP 125 mg having batch no.- ET70336, LT70790 and LT70791 manufactured and supplied by M/s Omega Biotech Ltd. were found to be "**Not of Standard Quality**". Also after analysis of the drug samples, CDL, Kolkata in its report has declared that the sample of LT70790 and LT70791 of Cefuroxime Axetil Tablet IP 125 mg does not confirm to IP with respect to Identification and assay of Cefuroxime Axetil Tablet IP 125 mg and the samples are deemed to be **'spurious'** as per section 17B of the Drugs and Cosmetic Act 1940 and Rules made there under.

19. In view of the above said facts it is explicitly clear that the reply given by the firm M/s. Omega Biotech Ltd is not tenable either in fact or law and is therefore fit to be rejected.

20. It is also evidently clear that the drug Cefuroxime Axetil Tablet IP 125 mg having batch no. LT70790 and LT70791 manufactured and supplied by M/ s Omega Biotech Ltd. has been declared to be **'spurious'.** Thus in exercise of the provisions contained in clause 27 B (5) of the bid reference no.- BMSIC/DRUGS/15-05, the firm **M/s Omega Biotech Ltd, 7th Mile Stone, Saliyar, Dehradun Road,Roorkee-247667, Uttarakhand** is hereby **blacklisted for a period of two (02) years from the date of the issue of this order.**

21. The **Performance Security/Bank Guarantee** submitted by the firm for the said tender **shall also stand forfeited** in accordance with the terms and conditions of the Contract.

22. This order shall not be applicable for the previously procured drugs and for the purchase orders issued before the date of issue of this order and the pending payments shall be released only after the quality clearance against each received batch. All executed rate contract with M/s Omega Biotech Ltd is hereby suspended along with the release of this order.

Sd/-

(Managing Director)

Memo No- BMSIC/50040/15-2017/ 6765 **Date:-** 04**/02/2020**

Copy To: -

1. **The Principal Secretary, Department of Health, Govt. of Bihar for his kind information please.**
2. **State Drug Controller, Bihar for his information and necessary action.**
3. **Drug Controlling and Licensing Authority, Uttarakhand for his information and necessary action.**
4. **The CGM (Supply Chain), BMSICL for his information and necessary action.**
5. **The GM (Finance)/GM(Logistics)/GM(Procurement), BMSICL for his information and necessary action.**
6. **M/s Omega Biotech Ltd, 7th Mile Stone, Saliyar, Dehradun Road, Roorkee-247667, Uttarakhand for information.**
7. **The IT Section, BMSICL for his information and necessary action.**

04/2/20

(Managing Director)