



# ODISHA STATE MEDICAL CORPORATION LTD.

(A Govt. of Odisha Undertaking)

Assuring Quality, Saving lives

No. 116 95 /OSMC/QA/971/2017

Date : 17.11.2017

## ORDER

M/s. Scott-Edil Pharmacia Ltd., 54-55, Industrial Area, Phase-II, Chandigarh – 160002 was placed with orders to supply Ciprofloxacin Eye/Ear Drop vide purchase order No. CR16616 dtd.04.11.2016. The firm supplied the said drug in a number of batches out of which two (02) batches have been declared as “Not of Standard Quality” (NSQ) by three (03) empanelled approved NABL accredited laboratories, which were communicated to the supplier by enclosing the copies of test reports vide this office letter No.8547 dtd.18.08.2017.

The details of batches of subject drug and the reason for declaring the sample of above said batches as NSQ are mentioned below.

Sl. No.	Batch No.	Mfg. Dt.	Exp. Dt.	Mfd. By	Ref. PO/ Date	Reason for declaring NSQ
1	ED6138	11/2016	10/2018	M/s. Scott-Edil Pharmacia Ltd., 56, E.P.I.P, Phase-I, Jharmajra, Baddi, Dist-Solan, (HP) - 173205	CR16616 04.11.2016	Sample does not comply the description test as per monograph prescribed in IP
2	ED6142	12/2016	11/2018			Sample does not comply the description test as per monograph prescribed in IP

In view of the above M/s. Scott-Edil Pharmacia Ltd. was issued with Show Cause Notice vide this office letter No.8568 dtd.19.08.2017 seeking explanation within seven days of receipt of the letter as to why it shall not be derecognised/blacklisted for the item Ciprofloxacin Eye/Ear Drop for a period of three (03) successive years in accordance with PO Clause No. 5(h)(ii) read with Bid Condition No. 6.39.8.1(ii) of Bid Reference No. OSMCL/2016-17/DRUGS-DHS-GR/01.

The noticee-firm was also intimated vide this office letter No.9491 dtd.22.09.2017 to avail the opportunity to be heard in person or through authorised representative on 11.10.2017. In response to the same no one from the noticee-firm appeared before the Authority on 11.10.2017. But the Authorised signatory of the firm in his letter dtd.22.09.2017 has submitted reply to this office Show Cause Notice.

In the reply, the authorised signatory of the firm has stated the followings.

- They have reviewed Batch Manufacturing Record (BMR) & Batch Packing Record of said batch and found satisfactory, no deviation has been observed in any manufacturing & product packing process.
- They have analysed the control sample of the said batch and results were found satisfactory and were found within specified limits, no any vials fail in physical appearance.
- They have reviewed their analytical data (chemical analysis & microbial analysis) of said batch and results are within specified limits, no deviation has been observed in the analysis of said batch.
- They have investigated the matter and as Ciprofloxacin is sensitive to moisture and temperature, the probable cause for non conformance of testing parameters of sample might be due to storage at uncontrolled temperature and humidity condition.

*Ravindra*

(P.T.O)

- v) Their in-house testing results are found within specified limit and satisfactory and hence they would like to challenge the test report of Govt. Analyst.

In response to above reply it is seen that as per monograph of IP 2014, Ciprofloxacin Eye Drop is a sterile solution of Ciprofloxacin Hydrochloride in Purified Water. So far as the storage conditions are concerned, as per IP, the preparation should be protected from light. As per literature survey Ciprofloxacin Eye Drops need to be stored at room temperature and away from excess heat and moisture. In this case it is seen that the total supply of the subject batch of drug has been stored at controlled temperature, heat & moisture. Hence, the adverse effect due to all the above factors does not arise at the time of storage. The sample has been tested at empanelled approved NABL accredited laboratories and the test reports of three laboratories reveal- **i) the solution is white in colour with sediment setting down ii) off white liquid with suspended particles iii) vials found with turbid liquid (haziness)**. Presence of suspended particles and haziness of the sample conformed by laboratories is a serious defect.

Further, in response to reply of the manufacturer at point (v) above, it is seen that the samples of said two batches of subject item were tested at approved NABL accredited laboratories empanelled by OSMCL and not in Govt. Statutory Laboratories.

As per terms and conditions of the tender in case of NSQ report of the sample from the approved NABL accredited laboratory empanelled by OSMCL two other portions of the sample shall be sent to two different laboratories empanelled by OSMCL and the majority of status report (out of three laboratories reports) related to SQ/NSQ shall be treated as final report. When two or more than two batches of that item comes out to be NSQ, OSMCL shall derecognise/blacklist the defaulting supplier for that item for a period of three (03) successive years from the date of issue of letter to the concerned firm. In the present case samples of two batches of subject item have been declared as NSQ by three empanelled laboratories for each batch for not complying the description test as per monograph prescribed in IP, which is a serious defect. Since reports of empanelled laboratories shall be acceptable to both OSMCL and the supplier as per terms and conditions of the tender, the reply of the firm in response to Show Cause Notice is not admissible.

Therefore, as per PO Clause No. 5(h)(ii) read with Bid Condition No. 6.39.8.1(ii) of Bid Reference No. OSMCL/2016-17/DRUGS-DHS-GR/01, M/s. Scott-Edil Pharmacia Ltd., 54-55, Industrial Area, Phase-II, Chandigarh - 160002 having manufacturing unit at 56, E.P.I.P, Phase-I, Jharmajri, Baddi, Dist-Solan (HP) - 173205 is hereby derecognised/ blacklisted for the item Ciprofloxacin Eye/Ear Drop for a period of three (03) successive years from the date of issue of this order.

The Performance Security/ Bank Guarantee/ EMD submitted by the firm for the said item is hereby forfeited & the firm shall not be allowed to participate in the tender process of Odisha State Medical Corporation Ltd. for the said item.

**Memo No. 11696 /Dt. 17.11.2017**

Copy forwarded to M/s. Scott-Edil Pharmacia Ltd., 54-55, Industrial Area, Phase-II, Chandigarh - 160002, Punjab for information.

*Ravindra*  
16/11/17  
**R.P. Singh, I.A.S.**  
Managing Director, OSMCL

*Ravindra*  
**Managing Director**  
OSMCL

Continued...

**Memo No. 11697 /Dt. 17.11.2017**

Copy forwarded to the State Drugs Controlling Authority, Nagar Panchayat Bhawan, Sai Road, Baddi, Dist-Solan (HP) - 173205 for information and necessary action.

*Rainda*  
16/11/17  
**Managing Director**  
OSMCL

**Memo No. 11698 /Dt. 17.11.2017**

Copy forwarded to the Drugs Controller and Licensing Authority, Chandigarh Administration, Sector 16, Chandigarh-160016 for information and necessary action.

*Rainda*  
**Managing Director**  
OSMCL

**Memo No. 11699 /Dt. 17.11.2017**

Copy forwarded to the Drugs Controller, Odisha for information and necessary action.

*Rainda*  
**Managing Director**  
OSMCL

**Memo No. 11700 /Dt. 17.11.2017**

Copy forwarded to DHS/DMET, Odisha for information and necessary action.

*Rainda*  
**Managing Director**  
OSMCL

**Memo No. 11701 /Dt. 17.11.2017**

Copy submitted to the Commissioner-cum-Secretary to Govt., H & FW Dept. Odisha, for favour of kind information.

*Rainda*  
**Managing Director**  
OSMCL

**Memo No. 11702 /Dt. 17.11.2017**

Copy forwarded to all the divisions of OSMCL for information and necessary action.

*Rainda*  
**Managing Director**  
OSMCL

**Memo No. 11703 /Dt. 17.11.2017**

Copy forwarded to the Sr. Manager (IT), OSMCL for information and necessary action.

*Rainda*  
**Managing Director**  
OSMCL