



ODISHA STATE MEDICAL CORPORATION LTD.

(A Govt. of Odisha Undertaking)

Assuring Quality, Saving lives

Order No. : 12229 / OSMCL/QA/709/2018

Date : 10-08-2018

ORDER

M/s. Aculife Healthcare Pvt. Ltd., 5th Floor, Commerce House V, Beside Vodafone House, Corporate Road, Prahalad Nagar, Ahemadabad – 380051, Gujarat was placed with orders to supply I.V. Compound Sodium Lactate IP (Ringer's Lactate) 500ml bottle vide Purchase Order No. CR17556 dtd.07.10.2017. The firm supplied the drug in a number of batches, out of which seven (07) number of batches have been declared as "Not of Standard Quality" (NSQ) by two out of three approved NABL accredited laboratories empanelled by Odisha State Medical Corporation Ltd. (OSMCL), which was communicated to the supplier by enclosing the copies of test reports vide this office letter No. 5347 dtd.12.04.2018 under intimation to the Commissioner, Food and Drug Control Admn. (FDCA), Gujarat, Block-8, Dr. Jivraj Mehta Bhavan, 1st Floor, Gandhi Nagar – 382010 vide memo No. 5348 dtd.12.04.2018.

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

Sl. No.	Batch No.	Mfg. Dt.	Exp. Dt.	Ref. PO No. & Date	Reason for declaring NSQ	Mfd. By
01	1K76195	11/2017	10/2020	CR17556 07.10.2017	The said seven batches do not comply the test for sterility as per IP 2014	M/s. Aculife Health Care Pvt. Ltd., Sachana, Gujarat – 382150
02	1K76306	11/2017	10/2020			
03	1K76345	11/2017	10/2020			
04	1K76349	11/2017	10/2020			
05	1K76356	11/2017	10/2020			
06	1K76370	11/2017	10/2020			
07	1K76380	11/2017	10/2020			

In view of the above M/s. Aculife Healthcare Pvt. Ltd. was issued with Show Cause Notice (SCN) vide this office letter No. 5562 dtd.19.04.2018 seeking explanation within seven (07) days of receipt of the letter as to why it shall not be derecognised/blacklisted for the item Compound Sodium Lactate Injection (Ringer's Lactate) IP 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.

In reply to the SCN dtd.19.04.2018, the noticee-firm vide letter dtd.25.04.2018 requested the following so as to enable them to represent their case in respect of the charges levelled against them.

- i) Copy of full Test Reports with laboratory name and product details.
- ii) Twenty five (25) working days time limit and personal hearing after completion of time period.

(P.T.O)

In response to above, the noticee-firm was supplied with the copies of test reports and also allowed 25 working days time period and the date of personal hearing was fixed on 05.06.2018 vide this office letter No.6531 dtd.08.05.2018.

The representatives of the company appeared before the Managing Director, OSMCL on 05.06.2018 and submitted a copy of reply dtd.31.05.2018 to the SCN signed by VP (Corporate Quality Head) and the reply stated the followings.

“They have tested all the mentioned batches of subject drug in their in-house QC lab as well as one external NABL accredited laboratory (M/s. Bee Pharmo Labs, Mumbai) for sterility testing and found to be complied”.

In response to our memo No.5348 dtd.12.04.2018, the Food & Drugs Control Administration, Gujarat State vide letter No.52048/G dtd.03.05.2018 informed that since the test reports are not issued by Govt. Analyst in Form 13 under Drugs and Cosmetics Act 1940, it is not possible to initiate any action against the manufacturer. But investigation at manufacturer level would be carried out and finding of investigation will be informed to OSMCL in short of time.

The noticee-firm has also vide letter dtd.21.06.2018 intimated that Senior Drugs Inspector, Food & Drugs Control Administration, Ahmedabad, Rural Area Circle, Gandhinagar has visited the factory to assess the issue and has also drawn statutory samples of subject batches. The notice-firm has also requested to hold any decision/action till receipt of test reports and submission of the same to OSMCL.

It is to mention here that M/s. Aculife Healthcare Pvt. Ltd. In whose favour the Purchase Order was issued, has accepted the tender conditions and supplied the drug, therefore, after its drugs are being declared as NSQ, the firm cannot turn around and question the said Clause and ask the authorities to resort to the State Drug Analyst Reports.

As per terms and conditions of the 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, “In case of NSQ report of the sample from the approved NABL accredited laboratory empanelled by OSMCL two (02) other portions of the sample shall be sent to two different laboratories empanelled by OSMCL and 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 batches of the 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 present case samples of seven (07) batches of subject item have been declared as NSQ by two out of three empanelled laboratories for each batch for not complying the sterility test as per monograph prescribed in IP.

Continued.....

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 SCN is not sustainable in the eye of law and therefore liable to be rejected.

That, 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. Aculife Healthcare Pvt. Ltd., 5th Floor, Commerce House V, Beside Vodafone House, Corporate Road, Prahalad Nagar, Ahemadabad – 380051, Gujarat having manufacturing unit at Sachana, Gujarat – 382150 is hereby, derecognised/debarred for the item I.V. Compound Sodium Lactate IP (Ringer's Lactate) 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.

Yours faithfully,


Archana Pattnaik, I.A.S
Managing Director, OSMCL

Memo No. 12230 /Dt. 10.08.2018

Copy forwarded to M/s. Aculife Healthcare Pvt. Ltd., 5th Floor, Commerce House V, Beside Vodafone House, Corporate Road, Prahalad Nagar, Ahemadabad – 380051, Gujarat for information.


Managing Director,
OSMCL


Memo No. 12231 /Dt. 10.08.2018

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


Managing Director,
OSMCL

Memo No. 12232 /Dt. 10.08.2018

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


Managing Director,
OSMCL

(P.T.O)

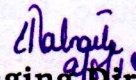
Memo No. 12233 /Dt. 10.08.2018

Copy forwarded to the GM – Operation (D & S)/GM (F & A), OSMC for information.


**Managing Director,
OSMCL**

Memo No. 12234 /Dt. 10.08.2018

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


**Managing Director,
OSMCL**