



ODISHA STATE MEDICAL CORPORATION LTD.

(A Govt. of Odisha Undertaking)

Assuring Quality, Saving lives

No.10955 /OSMC/QA/990/2017

Date: 25-10-2017

ORDER

M/s. Syncom Healthcare Limited, 502, Advent Atria, Chincholi Bunder, Malad (W), Mumbai – 400064 was placed with orders to supply Calcium & Vit-D3 Tablet vide purchase order No. CR16787 dtd.27.12.2016. 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 two (02) out of three (03) empanelled approved NABL accredited laboratories for batch No. SHT7040 & by three (03) empanelled approved NABL accredited laboratories for batch No. SHT7074, which were communicated to the supplier by enclosing the copies of test reports vide this office letter No.8823 dtd.30.08.2017.

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	SHT7040	02/2017	01/2019	M/s. Syncom Healthcare Ltd., D-42, IIE SIDCUL, Selaqui, Dehradun – 248197, Uttarakhand.	CR16787 27.12.2016	Sample does not comply the assay test of Vit. D3 as per label claim. The content of Vit. D3 as reported by two out of three labs empanelled by OSMCL are 178.32 IU (71.33%), 194.5 IU (77.8%) as against the label claim of 250 IU.
2	SHT7074	03/2017	02/2019			Sample does not comply the assay test of Vit. D3 as per label claim. The content of Vit. D3 as reported by three labs empanelled by OSMCL are 101.57 IU (40.63%), 173.32 IU (69.33%) & 132.2 IU (52.88%) as against the label claim of 250 IU.

In view of the above M/s. Syncom Healthcare Limited was issued with Show Cause Notice vide this office letter No.8977 dtd.01.09.2017 seeking explanation within seven days of receipt of the letter as to why it shall not be derecognised/blacklisted for the item Calcium & Vit-D3 Tablet 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 to avail the opportunity to be heard in person or through authorised representative on 11.10.2017. In response to the same the authorised representative of the firm appeared before the Authority on 11.10.2017 and submitted their reply vide letter dtd.05.10.2017 duly signed by the authorised signatory of the firm.

In the reply the authorised signatory of the firm has stated as follows :-

- i) They have checked BMR (Batch Manufacturing Record) & Control sample of above said two batches of subject item along with QC (Quality Control) testing report to confirm the results and found both the batches complying with IH (In House) specifications.
- ii) Both the batches were released for sale only after QC release and QA confirmation of BMR and BPR.

Ravindra

(P.T.O)

The authorised signatory of the firm in the said letter has expressed regret over declaration of concerned two batches as NSQ and has also shown readiness to go for product recall and replacement of both the batches with fresh ones.

But 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. The samples of said two batches of subject item have been declared as NSQ by the empanelled laboratories for not complying the assay of Vitamin D3 and content of Vitamin D3 is much less than the labelled amount, 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. Syncom Healthcare Limited, 502, Advent Atria, Chincholi Bunder, Malad (W), Mumbai – 400064 having manufacturing unit at D-42, IIE, SIDCUL, Selaqui, Dehradun – 248197, Uttarakhand is hereby derecognised/blacklisted for the item Calcium & Vit-D3 Tablet 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.

Rainindra
24/10/17

R.P. Singh, I.A.S.
Managing Director, OSMCL

Memo No. 10956 /Dt. 25-10-2017

Copy forwarded to M/s. Syncom Healthcare Limited, 502, Advent Atria, Chincholi Bunder, Malad (W), Mumbai – 400064 for information.

Rainindra

Managing Director
OSMCL

Memo No. 10957 /Dt. 25-10-2017

Copy forwarded to the Drugs Controller, Uttarakhand, Department of Medical Health and Family Welfare, Village-Danda Lakhond, Near Rajiv Gandhi Play Ground P.O. Gujrara, Sahastradhara Road, Dehradun, Uttarakhand, India for information and necessary action.

Rainindra

Managing Director
OSMCL

Continued....

Memo No. 10958 /Dt. 25.10.2017

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

Ravindra
24/10/17
Managing Director
OSMCL

Memo No. 10959 /Dt. 25.10.2017

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

Ravindra
Managing Director
OSMCL

Memo No. 10960 /Dt. 25.10.2017

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

Ravindra
Managing Director
OSMCL

Memo No. 10961 /Dt. 25.10.2017

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

Ravindra
Managing Director
OSMCL