ODISHA STATE MEDICAL CORPORATION LTD.
(A Govt. of Odisha Undertaking)
Assuring Quality, Saving lives

Order No. : 4147 **/OSMCL/QA/210/2015** **Date :** 07/04/2017

ORDER

M/s. Ozone Pharmaceuticals Ltd (Analytical Lab), Bahadurgarh, Haryana (hereafter for short, Analytical Lab) has been empanelled by Odisha State Medical Corporation for testing and analysis of drugs & for other purposes vide EOI No. OSMCL/QA/EOI/01/2015-16 with a valid rate contract for 2 years effective from 03.11.15 to 02.11.2017.

WHEREAS in course of the valid rate contract, 1130 nos of samples were sent to the Analytical Lab between 03.09.2015 to 17.12.2016, out of which 11 (eleven) nos of various samples were found to be NSQ, as declared by the concerned laboratory; And

WHEREAS one sample, namely, Tab. Cal. and Vit D-3 (70 Tabs) bearing Code No.TC16061881 was sent to the Analytical Lab vide this Office Sample Letter No.329/16-17 dt.28.07.2016. In reference to the same, the Analytical Lab has submitted the Test Report vide its Report No.OPLF03082016014 dt.5.08.2016 declaring the sample as of Standard Quality, based on which Test Report, the Batch was released for public distribution and use by the patients ; And

WHEREAS later on, the concerned Laboratory intimated the Drugs Controller, Odisha, Bhubaneswar regarding eight (08) nos of samples as NSQ (as required under Rule 150-E(g) of the Drugs and Cosmetics Rules, 1945), out of which one related to the sample Drug sent by OSMC and declared as SQ by the Analytical Lab in question. This fact was revealed vide Memo No.0410 dt.29.11.2016 of the Drugs Controller, Odisha addressed to the undersigned; And

WHEREAS it has been observed by this office that seven(07) out of eight(08) of the reports furnished by the Analytical Lab to the Drugs Controller, Odisha have been superimposed upon the same report submitted to this Corporation earlier. But one Test Report relating to Tab. Cal. and Vit D-3 under report No.OPLF03082016014 dt.05.08.2016 was submitted to the Drugs Controller, Odisha declaring the sample as NSQ in respect of assay claim of component Vit D-3 as 171.3 IU (i.e, below the limit of NLT 225 IU), while the report bearing no. TC16061881 dt.5.08.2016 was furnished to OSMC declaring the subject sample as of Standard Quality with altered value of assay claim of Vit D-3 as 349.68 IU (i.e, above the limit of NLT 225 I.U.). Therefore, obviously, the Analytical Lab has submitted contradictory Test Reports of the same sample to two different authorities i.e, this Corporation and Drugs Controller, Odisha in the manner stated above; And

(P.T.O.)

WHEREAS, for the reasons above stated, a notice was issued to the Analytical Lab vide our Letter No.42 dt.4.01.2017 to **show cause as to why it would not be blacklisted for testing and analysing the subject drug of the same batch in a totally contradictory manner i.e, to say while declaring one as of SQ, the other as of NSQ;** And

WHEREAS, in reply to the show cause dt.4.01.2017, the Analytical Lab requested for personal hearing and appeared before the undersigned on 09.01.2017 and furnished another Test Report of having retested the same sample vide Report No. OPLRT 03082016004 dt.5.08.2016 but the said report was found to be fraudulent. The Analytical Lab, obviously, resorted to such ex-facie fraudulent practice to shield its omission and commission in the earlier reports. The Test Report of the control sample could not have been done on 5.08.2016 as has been shown and submitted in course of personal hearing on 09.01.2017, even if it is presumed that the control sample was not destroyed after 30 days from the date of original Test Report; And

WHEREAS it is thus conclusively established beyond all ken of doubt that the Analytical Lab has furnished three (03) different Test reports for a particular sample and has claimed to have carried out the test and analysis in respect thereof on one date i.e, 5.08.2016 with different assay claim, at least in respect of the Test Reports submitted to the undersigned and the Drugs Controller, Odisha, Bhubaneswar and thus declaring the same as of Standard Quality and Not of Standard Quality.

The omission and commission as pointed out above is of such a nature that it cannot be overlooked as it relates to overall well-being of the patients; And

WHEREAS the plea advanced by the Analytical Lab in its reply to the show cause is devoid of any merit. Therefore, in the backdrop of the fact scenario and documents available on file, I am of the opinion that there is evidence to show that the said Analytical Lab is unerringly liable for action under clause 4.12.3 of the EOI-2015 and accordingly, it is blacklisted for 05 years from the date of this order to carry out test and analysis of drugs meant for human consumption.

This order entails all other consequential actions against the Analytical Lab.

07/04/17

Managing Director
OSMCL

Memo No. 4148 **/Dt.** 07/04/2017

Copy forwarded to M/s. Ozone Pharmaceuticals Ltd. (Analytical Lab), 639-640, M.I.E., Bahadurgarh – 124507, Haryana for information.

Managing Director
OSMCL

(Cont...)

Memo No. 4149 **/Dt.** 07/04/2017
Copy forwarded to the Drugs Controller, Haryana, Directorate of Health Services, Civil Dispensary, Sec – 20, Panchukla for information and necessary action.

07/04/17

Managing Director
OSMCL

Memo No. 4150 **/Dt.** 07/04/2017
Copy forwarded to the DHS, Odisha/ DMET, Odisha for information and necessary action.

Managing Director
OSMCL

Memo No. 4151 **/Dt.** 07/04/2017
Copy submitted to the Principal Secretary to Govt., H & FW Dept. Odisha, for favour of kind information.

Managing Director
OSMCL

Memo No. 4152 **/Dt.** 07/04/2017
Copy forwarded to all the divisions of OSMC for information and necessary action.

Managing Director
OSMCL