



# Uttar Pradesh Medical Supplies Corporation Limited

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Ref. No.: UPMSC/ MD/2019/15258

Date: 06 December, 2019

## OFFICE ORDER

The firm Revat Laboratory Pvt. Ltd, 8-2-700, Anushka Pride, 2<sup>nd</sup> Floor, Banjara Hills, Road No.12, Hyderabad-34 was declared L-1 in tender no- UPMSC/Drug-001/247, Dated-24/05/2018 for nine drugs including drug code D12011 drug ondansetron HCL oral solution IP 2mg/5ml : 30 ML and vide this office letter no-(1234 /UPMSCL/drugs/LOI/2018 dated-10.10.2018), the letter of Intent (LOI) was issued to firm.

The firm Revat Laboratory Pvt. Ltd had supplied batch No- ROSS-9022 and ROSS-9025 of drug Ondansetron HCL oral solution IP 2mg/5ml : 30 ML against purchase order no- UP/UP/HO/19/572/2 (10281910185) dated-29/05/2019, to different health facilities of Uttar Pradesh.

Drug sample of above two batches were collected from UPMSC transport nagar warehouse and sent to NABL accredited empanelled laboratory of UPMSC (Alcatec Research Laboratory India Pvt. Ltd), Alcatec Research Laboratory declared the above two batches i.e ROSS-9022 and ROSS-9025 as "Not Of Standard Quality" as defined in drug and cosmetic act 1940 & Rules made thereunder because above two batches does not comply with respect to Uniformity of fill volume (Batch No- ROSS-9022, Report No-ARLDF-1190930036 dated-05.10.2019 and Batch No- ROSS-9025, Report No- ARLDF-190930037, dated-05/10/2019).

According to Tender condition 11(ii), again the two sample of above said drug batches were sent to two different empanelled NABL accredited laboratories i.e Shree Balaji Test Lab (Pvt.) Ltd. The Batches ROSS-9022 & ROSS-9025 were declared as "Not of Standard Quality" by Shree Balaji test Lab (Pvt.) Ltd, because the both batches does not comply with respect to uniformity of volume (Batch No-ROSS-9022 Report No-SBTLF-021119005 dated-11.11.2019 and Batch No-9025 Report No-SBTLF-021119006, Dated-11.11.2019). The Batch ROSS-9025 declared as Standard Quality By ITL Lab pvt. Ltd (batch no- ROSS-9022, Report No-D201911040019 date-09/11/2019 and batch No-ROSS-9025, Report No-D2019110400209 dated-08/11/2019). Finally drug batch No-ROSS-9022 & ROSS-9025 were declared as "Not of Standard Quality" on the basis of three laboratory report & tender condition 11(ii).

A copy of Letter sent to CMO/CMS of health facilities of UP (Letter No-UPMSCL/QC/2019/14316, dated-26.10.2019) was sent to firm on 26.10.2019. In the response dated-31.10.2019, the firm has stated that-

- I. Alcatec research laboratories India Pvt. Ltd has done analysis using 15 bottles only for both batches and have not done the repeat test as suggested in IP before issuing the report, hence the report should not be considered as authentic as they did not follow the guidelines of IP.
- II. Firm has verified the credentials of Alcatec in the NABL website for the scope of analysis for products and in the scope for analysis the alcatec laboratory of liquid oral preparation to do analysis of liquid oral preparation. Hence they are not bona fide for issuing analytical report for oral liquid preparation.
- III. Average net fill volume mentioned in the report by the empanelled laboratory for both the batches are in line with and within the permissible limits as per IP 2018.
- IV. Firm has requested to send the sample to two laboratories as per the tender clause.

Notice regarding supply of "Not of standard Quality" Batch No-ROSS-9022 & ROSS-9025 was sent to firm Revat Laboratory Pvt. Ltd on 19/11/2019 and all three analytical laboratory report sent to firm on 30/11/2019. In the response dated 29.11.19, firm has stated that-

- I. Report issuing laboratory Alcatec research laboratory india pvt ltd do not have scope and accreditation to conduct analysis for liquid oral preparation and the laboratory has not conducted analysis as per IP 2018, Hence their report does not stand valid and must not be taken in to consideration:





- II. Regarding drug sample batches sent to further two different laboratories firm has stated that both laboratories have not done the analysis as per IP 2018.
- III. Firm has requested to provide 7 days time to submit detailed reply with all supporting document after getting the analysis done rigidly as per 2018.


In the response dated-04/12/2019 which was received to UPMSCL on 05/12/2019 the Firm has stated-

- I. The report issuing laboratory M/s Alcatec Research laboratory do not have the scope and accreditation of NABL to conduct analysis for liquid oral preparation. Firm had submitted the copy from NABL site. The firm stated that above laboratory did not conduct the analysis as per the IP 2018. Report of the Alcatec research laboratory should not be considered on the basis of above.
- II. The firm have submitted the copy of IP 2018 for content of packed dosage form as annexure-II "The above specification of IP 2018" (for content of packaged dosage forms) clearly states "The volume of contents of the 10 container is to be determine and if this requirement is not met, determine the net volume of the content of 10 additional container. On the above basis the Alcatec have not tested the product as per specification of IP 2018 protocol and submitted wrong report.
- III. The above batches sample are lifted for analysis in AP and sent for testing to the Government analyst Drug control laboratory in Andhra Pradesh. The Government analyst had declared both the batches as Standard Quality in respect of uniformity of volume and average volume.
- IV. M/s Balaji test House has declared the sample as of Standard Quality without performing the tests as per the IP 2018 protocols as they don't have the required quantity of sample to test the product.
- V. As the product of both the batch number are declared as Standard Quality by the Government analyst are treated as final as per the tender condition, The report from private labs should be superseded and the product with both the batches should be considered as Standard Quality.
- VI. Firm had supplied the corporation the product of Standard Quality and thereby not to be subjected to any penal action.

The firm Revat Laboratory Pvt. Ltd has provided response regarding average net volume but the UPMSCL empanelled laboratories had declared both batches Not of Standard Quality with respect to uniformity of volume. The Alcatec Research Laboratory India Pvt. Ltd had provided the detailed NABL scope of accreditation of Laboratory in which they have mentioned that on the basis of this scope they are carrying out the sample testing of oral suspension. The UPMSCL Empanelled Analytical Laboratories had done analysis of drug sample batches as per IP 2018 as evident from there analytical reports. The firm has submitted government analyst report from drug control laboratory in Andhra Pradesh. The Report of government analyst Andhra Pradesh cannot be considered as conclusive evidence because sample was not tested from the supplied quantity of the above drug batches to UPMSCL.

All the Bidders including the firm in question is well versed with the Terms and conditions of tender Document which provides that the drug sample shall be sent to the NABL accredited laboratory empanelled by UPMSCL and if the drug is reported to be "Not of standard Quality" the retained sample shall be sent to other two NABL concluded that the drug is "Not of Standard Quality" it is worth mentioning here that two out of three NABL accredited laboratories empanelled by UPMSCL have reported the drug to be "Not of Standard Quality".

In above case final report is "Not of standard Quality" on the basis of three analytical laboratory test report. Thus firm Revat Laboratory Pvt. Ltd has violated the tender clause No. 13(i) "If two batches of any drug supplied by the supplier is found not of standard quality, Then the supplier shall be blacklisted for that particular drug for a period of three (3) year" by supplying "Not of Standard Quality" two batches (ROSS-9022 & ROSS-9025) of the Drug Ondansetron HCL oral solution IP 2mg/5ml : 30 ML to different health facilities of Uttar Pradesh. Hence the Drug Ondansetron HCL oral solution IP 2mg/5ml : 30 ML, of the firm Revat Laboratory Pvt. Ltd is hereby blacklisted for three years from the date of this order.

  
Managing Director  
UPMSCL

**Copy: To following for information and necessary action:-**

1. Principal Secretary, Medical Health & Family Welfare, UP;
2. Secretary, Medical Health & Family Welfare, UP;
3. Mission Director, National Health Mission (NHM);
4. Director General, Medical & health Services, Swasthya Bhawan, UP;
5. Director General, family Welfare, Directorate family welfare UP;
6. CMO ; All Distt of Uttar Pradesh
7. CMS ; All Distt ( Male,Female & Combined ) Hospital of Uttar Pradesh
8. All Section Incharges of UPMSC.
9. Revat Laboratory Pvt. Ltd, Revat Laboratory Pvt. Ltd, 8-2-700, Anushka Pride, 2<sup>nd</sup> Floor, Banjara Hills, Road No.12,Hyderabad-34

Managing Director  
UPMSC