

Uttar Pradesh Medical Supplies Corporation Limited

Registered Office: SUDA Bhawan, 7/23/Sector-7, Gomti Nagar Extension, Lucknow-226010
E-Mail: Info@upmscl.in Website: www.upmscl.in Contact Number: 0522-2838102

Letter No.: UPMSCl/MD/2019/14489

Date: : 2 Nov.2019

OFFICE ORDER

The Firm Omega Pharma Khasara No.482, Village Saliyar, Roorkee-247667 Uttarakhand was declared L-1 in tender No.-UPMSCL/Drugs-001/247 dated 24/05/2018 for five drugs including drug code no. D05028 Erythromycin Stearate Tablets 250mg & vide this office letter No. (1228/UPMSCL/DRUGS/LOI/2018 dated 10/10/2018), the letter of intent was issued to Firm Omega Pharma.

The Firm Omega Pharma had supplied batches no. GPT003 (DM-10/2018, DE-09/2020) & GPT005 (DM-10/2018, DE-09/2020) against P.O. no-UP/UP/HQ/ 18/65/3(10281862573) dated 03/11/2018 of drug Erythromycin Stearate Tablets 250mg to different health facilities of Uttar Pradesh.

Drug sample of batch-GPT003 was collected on 28/01/2019 by Drug Inspector Central Drugs Standard Control Organisation (North Zone) Ghaziabad (Memorandum-NZ/SMP/DVS/A-079/2018-19/5460 Date-28/01/2019) and sent to Govt Analyst Central Drugs Laboratory Government of India Kolkata. Result (Report no.-32-1/2019-SS/DCA(N)-70/504, Dated-16/05/2019) declared from the above laboratory on 16.05.2019. According to the analysis report "The sample does not Conform to I.P. with Respect to Dissolution hence declared "Not Of Standard Quality".

Notice regarding supply of "Not of Standard Quality" for batch no GPT003 was sent to Firm Omega Pharma on 05/08/2019 (Ref. No.: UPMSCl/QC/2019/11928) and response was given by Firm by letter dated 09/08/2019 which was received to UPMSCl on 03.09.2019. In the response, the firm has written that:-

1-That we have manufactured the drug Tab. Erythromycin Sterate 250mg Batch No.-GPT003 as of standard quality in respect of all parameters including the Dissolution test and release for the sale after getting an approval from our well equipped quality control Laboratory.

2-That as per tender agreement or contract before supply to different health facilities the drug was tested by UPMSCl empanelled Govt Approved Laboratory M/s Shree Balaji test lab pvt Ltd., vide test report no SBTLF-271018101 dated-29/10/2019. After receiving the copy of test report drug clearance permission (Certificate No.-DCC/UPMSCL/2018/1659/110 dated-26/11/2018) was taken from Quality Control Department of UPMSCl.

3-That Firm does not agree with the Govt analyst report Central drugs Laboratory, vide Report no.-32-1/2019-SS/DCA(N)-70/504 Dated-16/05/2019. The Firm manufactures standard quality drugs and gets the test done by well equipped Quality Control Laboratory.

4-That after receiving the letter and Govt. Analyst Report from Drug Inspector Central Drugs Standard Control Organisation (North Zone) Ghaziabad regarding the above said drug, the firm had tested their control sample from Govt. Approved Lab. M/s Catts Labs & Research Pvt. Ltd. And the same was declared of "Standard Quality" vide test report no.-CDM02201907 Dated-24/07/2019 including Dissolution Test.

5-That even then the firm is ready to recall the above said drug batch from different health facilities.

Another batch of said drug-GPT005 was collected on 05.02.2019 by Drug Inspector Central Drugs Standard Control Organisation (North Zone) Ghaziabad (Memorandum-NZ/SMP/PK/A-57/2018-19/5677, Date-05/02/2019) and sent to Government Analyst Central Drugs Laboratory Government of India Kolkata. Result (Report no.-32-1/2019-SS/DCA(N)-92/505 Dated-16/05/2019) declared from the above laboratory on 16.05.2019. According to analysis report "The sample does not conform to I.P. with Respect to Dissolution hence declared "Not Of Standard Quality".



Uttar Pradesh Medical Supplies Corporation Limited

Registered Office: SUDA Bhawan, 7/23, Sector-7, Gomti Nagar Extension, Lucknow-226010
E-Mail: info@upmsc.in Website: www.upmsc.in Contact Number: 0522-2838102

Notice regarding supply of "Not of Standard Quality" drug Tab Erythromycin Sterate 250mg batch no GPT005 was sent to Firm Omega Pharma on 18/10/2019 (Ref. No.: UPMSC/QC/2019/13956) and seven days time was given for response but no response given by firm till 26.10.2019. Further as a last opportunity another notice (Notice No-UPMSCL/QC/2019/14317) was sent to firm on 26.10.2019 and 5 days time i.e. up to 30.10.19 at 5 PM was given for the response. Response of Firm was received on 30.10.2019 (Letter dated ; 29.10.2019). In the response Firm Omega Pharma has written ;

1. That firm manufactured the drug Erythromycin stearate tab 250mg Batch No- GPT003 and Batch No- GPT005 as of "Standard Quality" in respect of all parameters including "Dissolution Test" and release for the sale after getting an approval from our well equipped quality control laboratory.
2. That as per tender agreement or contract before supply to different health facilities, the drug was tested by UPMSC empanelled Government approved laboratory M/s Shree Balaji Test Lab Pvt. Ltd, vide test report no. SBTLF-271018101, dated-29.10.2019 (for Batch no-GPT003) & test report no. SBTLF-311018103, dated-01.11.2018 (for batch no-GPT005). After receiving the copy of "Standard Quality" test report drug clearance permission (Certificate no. DCC/UPMSCL/2018/1659/110, dated-26.11.2018 for Batch no-GPT003 and Certificate no. DCC/UPMSCL/2018/1661/112, dated-26.11.2018 for Batch no-GPT005) was taken from Quality Control Department of UPMSC.
3. That firm does not agree with the Government Analyst report, Central Drugs Laboratory, vide test report no-32-1/2019-SS/DCA/(N)-70/504 dated 16.05.2019 and test report no- 32-1/2019-SS/DCA/(N)-92/505, dated-16.05.2019 on form-13. The firm manufactures standard quality drugs and get the tests done by well equipped Quality Control laboratory M/s Shree Balaji Test Lab (Pvt.) Ltd, vide the said laboratory had declared the Batch no-GPT003 (test report no-SBTLF-271018101, dated-29.10.2018) and Batch no-GPT005 (test report no-SBTLF-311018103, dated-01.11.2018) as of "Standard Quality".
4. That after receiving the letter from Drug Inspector CDSCO (North zone) Ghaziabad regarding the above said drug with Government Analyst report. The Firm had replied with in time and challenged the same of Government Analyst report on Form-13, apart from this the firm had tested their control sample from Government approved Lab. M/s Catts labs & Research Pvt. Ltd and M/s Shree Krishna Analytical Services and the same was declared of "Standard Quality" vide Test report no. CDM02201907 dated-24.07.2019, and test report no.SKF-110919102, dated-13.09.2019 including "dissolution test".
5. That after receiving the sample portion bearing Batch No-GPT003, which the Drug Inspector CDSCO (North Zone) Ghaziabad has provided to firm. The firm had sent the 50 tablets to Government approved laboratory M/s Shree Krishna Analytical Services, A-5/4, mangolpuri Industrial area, phase-II, New Delhi-110064 for test and analysis and the report given by above laboratory is of ""Standard Quality" including Dissolution Test vide test report no-SKF-110919101, dated-13.09.2019.
6. That further the sample portion bearing Batch no-GPT003 which the drug Inspector CDSCO (North Zone) Ghaziabad has provided to firm. The firm has sent 50 tablets to Government approved laboratory M/s Shree Balaji Test Lab (Pvt.) Ltd, C-Naraina Industrial Area- Phase-I, New Delhi-110028 for test and analysis. The Government approved laboratory M/s Shree Balaji Test Lab (Pvt.) Ltd found the same of "Standard Quality" including "Dissolution Test" vide test report no- SBTLF-130919127 dated -16.09.2019.
7. That the firm is not satisfied with the finding of Government Analyst Report on form-13 so they are already challenging the same. The report of re-test or CDL Kolkata is still awaited. So In the interest of justice it is essential to wait the report of re-test or re-analysis from CDL Kolkata, In these circumstance no any coercive action against firm should be taken.



Uttar Pradesh Medical Supplies Corporation Limited

Registered Office: SUDA Bhawan, 7/23, Sector-7, Gomti Nagar Extension, Lucknow-226010
E-Mail: info@upmscl.in Website: www.upmscl.in Contact Number: 0522-2838102

The letter of the firm dated-29/10/2019 was given due consideration. At this juncture, it would be worth mentioning that till date the above said test reports (Report no.-32-1/2019-SS/DCA(N)-70/504 Dated-16/05/2019 and Report no.-32-1/2019-SS/DCA(N)-92/505 Dated-16/05/2019) sent by Drug Inspector Central Drugs Standard Control Organisation (North Zone) Ghaziabad has neither been cancelled nor annulled by any higher authority and therefore the same is still operative.

In above case final report of the drug (Tab. Erythromycin Sterate 250mg) batches GPT003 & GPT005 as "Not Of Standard Quality" on the basis of analytical test report given by Government Analyst Central Drugs Laboratory Kolkata. Thus firm Omega Pharma has violated the *Tender clause No.13.(i)* "If two batches of any drug supplied by a vendor/supplier/firm is found not of standard quality, then the vendor/supplier/firm shall be blacklisted for that particular drug for a period of three years." And violated *Agreement clause no-4 (a)*, "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 year.", by supplying "Not Of Standard Quality" (NSQ) two batches (GPT003 & GPT005) of the drug Tab. Erythromycin Sterate 250mg to different health facilities of Uttar Pradesh . Hence, the Drug Tab. Erythromycin Sterate 250mg of the firm M/s Omega Pharma is, hereby, blacklisted for three years from the date of issue of this order.

Managing Director
UPMSCL

Endorsement No: UPMSCL/QC/2019/14489

Date: 2 Nov. 2019

Copy: To following for information & necessary action.

- (1) The Principal Secretary, Department of Medical, Health and family welfare, Uttar Pradesh.
- (2) Secretary, Department of Medical, Health and family welfare, Uttar Pradesh.
- (3) Mission Director, National health mission (NHM), Uttar Pradesh.
- (4) Director General, Medical and Health Services, Swasthy Bhawan, Uttar Pradesh.
- (5) Director General, Family Welfare, Family Welfare Directorate, Uttar Pradesh.
- (6) M/s Omega Pharma Khasara No.482, Village Saliyar, Roorkee-247667, Distt. Haridwar, Uttarakhand

Managing Director
UPMSCL

