



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/2019/13710

Date: 07/10/2019

Office Order

The Firm, M/s-Grampus Laboratories, Johron industrial area, Kala Amb Distt. Sirmor (Himachal Pradesh) was declared L-1 in tender No.-UPMSCL/Drugs-003/316 dated 12/06/2018 for three drugs including drug code no. D08005, Neomycine Sulphate, Polymixin-B sulphate & Bacitracin Zinc Powder, 10gm bottle & vide this office letter No. 1144/UPMSCL/Drugs/LOI/2018 dated 10/10/2018, the letter of intent was issued to firm Grampus Laboratories.

The firm Grampus Laboratories had supplied batch no-GLEP-181006 (DM-10/2018, DE-09/20) against PO no-UP/UP/HQ/18/18/2/10281861828 dated 03/11/2018 and batch No.-GLEP-181020 (DM-10/2018, DE-09/20) against P.O. No.- UP/UP/HQ/19/274/1/ (10281905860) dated 26/03/2019 of drug Neomycin Sulphate, Polymixin-B Sulphate & Bacitracin Zinc to different health facilities of Uttar Pradesh.

Drug Sample of Neomycin Sulphate, Polymixin-B Sulphate & Bacitracin Zinc Powder Batch No. GLEP- 181006 (D/M10/ 18DE/2020) supplied by the firm M/s Grampus laboratories was collected (Memorandum-NZ/SMP/DR/A-071/2018-19/4971 dated- 31.12.2018) by drug inspector CDSCO (CDSCO is the National Regulatory Authority) North Zone. According to the Analysis report (LSD/RDTL/1700/18-19 dated - 28.06.2019), the sample is "Not of Standard Quality" as defined in the Drugs and Cosmetics Act 1940, and Rules there under, for the reasons given as; "the sample does not conform to claim as per Patent and Proprietary in respect to the Identification". Thus, as defined under section 17-B of the Drugs and Cosmetics Act 1940, the said drug manufactured and supplied by the M/s Grampus Laboratories is 'Spurious'.

Notice regarding supply of "Not of Standard Quality/ Spurious Drug" for Batch No. GLEP-181006, was sent to firm M/s Grampus Laboratories on 01/08/2019(Ref. No. 11830/UPMSCL/QC/2019) and response was given by firm by letter (Ref No. GL/UPMSCL/C-1 Dated: 07.08.2019) & (Ref No. GL/UPMSCL/C-2 dated: 09.08.2019) to UPMSCL. In the response the firm has submitted two analytical reports of Neomycin Sulphate, Polymixin-B Sulphate & Bacitracin Zinc Powder Batch No. GLEP- 181006 as of "Standard Quality" from Sri Ram Institute for industrial research New Delhi & Oxygen analytical laboratories, Baddi. The firm has submitted that it does not agree with the report of Government analyst provided by the Drug Inspector, CDSCO because the Government Analyst, RDTL, Chandigarh has declared the sample

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as "Not of Standard Quality" on the basis of Identification and the test for microbiological assay has not been conducted.

Further, another drug sample of Neomycin Sulphate, PolymixIn- B Sulphate & Bacitracin Zinc Powder Batch No. GLEP- 181020 (DM-10/ 18/DE-09/20) supplied by the firm M/s Grampus laboratories was collected (Memorandum- NZ/SMP/DN/2018-19/48/4537 dated- 24.12.2018) by Drug Inspector, CDSCO, North Zone. According to the Analysis report (LSD/RDTL/1629/18-19 dated - 28.06.2019) the sample is "Not of Standard Quality" as defined in the Drugs and Cosmetics Act 1940, and Rules there under for the reasons given as, "the sample does not conform to claim as per Patent and Proprietary in respect to the Identification". Thus, as defined under Section-17-B of the Drugs and Cosmetics Act 1940, the said drug manufactured and supplied by the M/s Grampus laboratories is 'Spurious'.

Notice regarding supply of "Not of Standard Quality/ Spurious Drug" for Batch No. GLEP- 181020 was sent to firm M/s Grampus Laboratories on 21/09/2019 (Ref. No. 13319/UPMSCL/QC/2019). The response was given by the firm through letter vide GL/UPMSCL/C-8 dated 01.10.2019. In the response firm has mentioned that they have already stated all the necessary facts and points regarding the sample in question in the response dated 07.08.2019 and 09.08.2019, and also stated their disagreement with the report issued by the Government Analyst, RDTL, Chandigarh and they have clearly stated their intent to challenge the report/adduce evidence in contravention to the report issued by the Government Analyst, RDTL, Chandigarh. The firm has also submitted that they (firm) have received notice dated 23.09.2019 from the concerned Drug Inspector, CDSCO, Ghaziabad on 28.09.2019 by speed post. The firm has mentioned in their response that they have communicated with the drug inspector vide their letter No. NEO/CDSCO/C-2 dated 01.10.2019 sent by speed post and challenged the report/adduce evidence in contravention to the report issued by the Government Analyst, RDTL, Chandigarh, as per Drug and Cosmetics Act 1940 and Rules 1945 of the act. The firm has mentioned that due to their challenge/adduce letter report issued by Government Analyst (form-13) loses its character of conclusive evidence and it is only and only the report of Director Drugs Laboratories (Form-2) shall be the conclusive evidence. However, by means of the letter dated 01.10.2019, the firm has stated that it has challenged the report of the Drug Inspector in prescribed form no-2 before the Director Drugs Laboratories and thus the reports

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(LSD/RDTL/1700/18-19 dated 28.06.2019 and LSD/RDTL/1629/18-19 dated 28.06.2019) cannot be treated as conclusive evidence.

The letter of the firm dated 01.10.2019 was given due consideration. At this juncture, it would be worth mentioning that till date the above said reports (LSD/RDTL/1700/18-19 dated 28.06.2019 sent by the Drug Inspector on 18/07/2019 and LSD/RDTL/1629/18-19 dated 28.06.2019 sent by the Drug Inspector on 23/08/2019) has neither been cancelled nor annulled by any higher authority and therefore the same is still operative.

Firm M/s Grampus Laboratories has violated the tender Clause No.-13 (V) of Tender no-UPMSCL/Drugs-003/316 dated 12/06/2018 i.e., 'The Supplier shall be blacklisted for a period of 3 years if any of the drugs supplied is declared spurious or adulterated by the regulatory authority.' and violated Agreement Clause No.-4 (C), 'The supplier shall be blacklisted, for a period of 3(Three) years if any of the drugs supplied is declared spurious or adulterated by the regulatory authority.', by supplying two "SPURIOUS" drug batches (GLEP-181006 and GLEP-181020) of Neomycin Sulphate, Polymixin - B Sulphate & Bacitracin Zinc Powder to different health facilities of Uttar Pradesh. Hence, firm M/s Grampus Laboratories is hereby blacklisted for Three Years from the date of issue of this order.

Managing Director
UPMSCL

Endorsement No.: UPMSCL/MD/2019/

Date: 07/10/2019

Copy: To the following for information and necessary action.

1. The Principal Secretary, Department of Health and family welfare, Uttar Pradesh.
2. Mission Director, NHM, UP
3. Director CDSCO, North Zone, Ghaziabad, UP
4. Director General, Medical and Health Services, Swasthaya Bhawan, U.P.
5. Director General, Family Welfare, U.P.
6. M/s Grampus Laboratories, Jhron Industrial Area, Kala Amb District Sirmor (H.P.)

Managing Director
UPMSCL