(A Govt. of Uttar Pradesh Undertaking)

Registered Office : SUDA Bhawan, 7/23, Sector-7, Gomti Nagar Extension, Lucknow-226002 E-Mail: <u>quality@upmsc.in</u> Website: <u>www.upmsc.in</u> Contact Number: 0522-2838102

Ref. No.: UPMSCL/MD/QC/2025/ 24

Date : 04 - April -2025

Office Order

Concept Pharmaceutical Ltd. has rate contract with UPMSCL for the supply of drug "Cefotaxime Sodium IP 1 gm dry powder Injection in vial". Concept Pharmaceutical Ltd. has supplied drug "Cefotaxime Sodium IP 1 gm dry powder Injection in vial" batch no. C21K802002 (Mfg. date- 12/2022 & Exp.date-11/2024), against Purchase Order no. UP/UP/HQ/22/884/2 (10282206240), dated 14.11.2022. Company also supplied batch no. C21K803040 (Mfg. date- 04/2023 & Exp.date-03/2025), against Purchase order no. UP/UP/HQ/23/694/2 (10282303922), dated 20.03.2023 and Purchase order no. UP/UP/HQ/23/1473/2 (10282306866), dated 06.07.2023. Company also supplied batch No.- C21K803016 (Mfg. date- 02/2023 & Exp.date-01/2025), against Purchase order no. UP/UP/HQ/23/475/2 (10282301808), dated 17.02.2023. to various District Drug warehouses of Uttar Pradesh Medical Supplies Corporation Ltd.

Earlier, notice (Ref. no. UPMSCL/MD/QC/2023/591 dated-10.08.2023) was sent to Concept Pharmaceutical Ltd. for "Not of Standard Quality" drug Batch No.- C21K802002 of drug "Cefotaxime Sodium IP 1 gm dry powder Injection. Drug batch (Batch no.- C21K802002) was declared "Not of Standard Quality" from Government Analyst.

Another, notice (Ref. no. UPMSCL/MD/QC2024/471 dated-23.07.2024) was sent to Concept Pharmaceutical Ltd. for "Not of Standard Quality" drug Batch No.- C21K803040 of drug "Cefotaxime Sodium IP 1 gm dry powder Injection. Drug batch (Batch no.- C21K803040) was declared "Not of Standard Quality" from Government Analyst.

Firm has provided the response vide letter ref. no. CPL/FDA/GEN/2024/187, dated 19/08/2024 which was received to UPMSCL via post on dated 29.08.2024. Company has written that they do not agree with Government Analyst report hence they have written letter to Inspector of Drugs, Bijnor, FDA, UP on 05.09.2023 and letter to Inspector of Drugs, Jaunpur, FDA, UP on 17.08.2024 that Company will challenge the report of drug batches i.e. batch no. C21K802002 and batch no. C21K803040 of drug "Cefotaxime Sodium IP 1 gm dry powder Injection. Company has not provided any conclusive evidence of challenging the both Government Analyst report till date. Response provided by company was given due consideration but not found correct and justifiable.

Reports declared "Not Of Standard Quality" by Government Analyst has neither been cancelled nor annulled by any higher authority and therefore the analysis report provided by Government Analyst for Drug batch no. C21K802002 and batch no. C21K803040 of drug "Cefotaxime Sodium IP 1 gm dry powder Injection remains conclusive report till date.

Another, notice (Ref. no. UPMSCL/MD/QC/2024/537 dated-02.08.2024) was sent to Concept Pharmaceutical Ltd. for "Not of Standard Quality" drug Batch No.- C21K803016 of drug "Cefotaxime Sodium IP 1 gm dry powder Injection. Drug batch (Batch no.- C21K803016) was declared "Not of Standard Quality" from Government Analyst. Company has not provided the response to notice dated 02.08.2024 by UPMSCL till date.

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Three "Not Of Standard Quality" reports which have been declared by Government Analyst for batch no. C21K802002, batch no. C21K803040 and batch no. C21K803016 are neither been cancelled nor annulled by any higher authority and therefore the analysis report provided by Government Analyst for Drug batch no. Batch no. C21K802002, batch no. C21K803040 and batch no. C21K803016 of drug "Cefotaxime Sodium IP 1 gm dry powder Injection remains conclusive report till date.

With above description it is clear that Company Concept Pharmaceutical Ltd. has supplied three "Not of Standard Quality" Drug batches (Batch no. C21K803016, batch no. C21K803040, and Batch no. C21K802002) to UPMSCL and thus violated the Condition of contract ; Clause no. 13 (Debarring & Blacklisting) sub clause (i) of Tender No. UPMSCL/Drugs-157/533 dated 12.01.2022 i.e. "If two batches of any drug supplied by a Company/firm is found not of standard quality, then the Supplier Company/firm shall be blacklisted for that particular drug for a period of three years".

Hence, the Company Concept Pharmaceutical Ltd is, hereby, blacklisted for the Drug "Cefotaxime Sodium IP 1 gm dry powder Injection for three years from the date of issue of this order.

Managing Director UPMSCL

Endorsement No.: UPMSCL/MD/QC/2025/24 Dated : 04- April -2025

Copy to the following for information & necessary action:

- 1. Finance Controller, UPMSCL to kindly ensure that payment is not processed for "Not of Standard Quality" declared drug batches.
- Drug Licensing & Controlling Authority, UP, Office of Commissioner, Food Safety & Drug Administration, Sec-C, Aliganj, Lucknow.
- 3. Senior Consultant Drug Procurement and Quality Control, UPMSCL
- 4. Consultant Drug Procurement, UPMSCL.
- 5. General Manager, Quality Control UPMSCL.
- 6. General Manager, Drugs, UPMSCL.
- 7. General Manager, Supply Chain, UPMSCL.
- 8. Manager, Legal, UPMSCL.
- 9. Manager, Quality Control, UPMSCL
- 10. Manager , IT, UPMSCL.
- 11. Project Manager, DVDMS, UPMSCL.
- 12. Incharge Warehouse Pharmacist, All Disrict Drug warehouses of UPMSCL.
- 13. Concept Pharmaceutical Ltd., B-801 Hubtown Solaris, N.S. Phadke Marg, Off. Teli Galli, Near Andheri Flyover, Andheri East Mumbai -400069

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> Managing Director UPMSCL

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