



Uttar Pradesh Medical Supplies Corporation Limited

(A Govt. of Uttar Pradesh Undertaking)

Registered Office: SUDA Bhawan, 7/23, Sector-7, Gomti Nagar Extension, Lucknow-226002

E-Mail: quality@upmsc.in Website: www.upmsc.in Contact Number: 0522-2838102

Ref. No.: UPMSCL/MD/QC/2025/ 724

Date : 26- Aug- 2025

Office Order

Kemecos India Private Limited has rate contract with UPMSCL for the supply of drug "Benzyl Benzoate Application: 25% w/w (-) 100 ml Bottle". Kemecos India Private Limited has supplied drug "Benzyl Benzoate Application: 25% w/w (-) 100 ml Bottle, batch no. batch no. BB-791, BB-793, BB-794, BB-795, BB-796, BB-798, BB-799, BB-802, BB-803, BB-804, BB-810, BB-811, BB-812 (All 13 Drug batches have Mfg. date 01/25 & Exp. date 12/26), and batch no. BB-816, BB-817, BB-818, BB-826, BB-833, BB-837, BB-838 , BB-843, BB-845 , BB-853, BB-863, BB-864, BB-865" (All 13 Drug batches have Mfg. date 02/25 & Exp. date 01/27). Ten Drug batches i.e. Batch no. BB-791, BB-793, BB-794, BB-795, BB-796, BB-798, BB-799, BB-802, BB-803, and BB-804 supplied against purchase order no. UP/UP/HQ/24/2128/1 (10282409644), dated 04.12.2024, Seven drug batches i.e. Batch no. BB-810, BB-811, BB-812, BB-816, BB-817, BB-818, BB-826, against purchase order no. UP/UP/HQ/24/2257/1 (10282410369), dated 20.12.2024, Eight drug batches i.e. Batch no. BB-837, BB-838 , BB-843, BB-845 , BB-853, BB-863, BB-864, BB-865 supplied against purchase order no. UP/UP/HQ/25/149/1 (10282500345), dated 11.01.2025. One drug batch i.e. Batch no. BB-833 supplied against purchase order no. UP/UP/HQ/24/2257/1 (10282410369), dated 20.12.2024 & purchase order no. UP/UP/HQ/25/149/1 (10282500345), dated 11.01.2025 to various District Drug warehouses of Uttar Pradesh Medical Supplies Corporation Ltd.

Earlier, notice (Ref. No. UPMSCL/MD/QC/2025/490, Dated 16.07.2025) was sent to Kemecos India Private Limited for supply of NSQ drug "Benzyl Benzoate Application: 25% w/w (-) 100 ml Bottle" batch no. BB-791, BB-793, BB-794, BB-795, BB-796, BB-798, BB-799, BB-802, BB-803, BB-804, BB-810, BB-811, BB-812, BB-816, BB-817, BB-818, BB-826, BB-833, BB-837, BB-838 , BB-843, BB-845, BB-853, BB-863, BB-864 and BB-865 on dated 16.07.2025. Firm has provided the response vide letter ref. no. KIPL/118/25-26, dated 21.07.2025 received to UPMSCL on 21.07.25 through e-mail and on 29.07.2025. through courier. Another letter (Letter ref no. KIPL/137/25-26 Dated ; 06.08.2025) sent by Firm which was received to UPMSCL on 18.08.2025.

Following are the response of UPMSCL against representation letter dated 21.07.2025 & 06.08.2025 by Firm Kemecos India Private Limited ;

- (i) In the tender (No. UPMSCL/Drugs-208/52, dated 08.03.2024), condition no. 11 clearly states : "Confirmatory quality testing of supplied drug batches shall be as per the UPMSCL Quality Policy." At the time of the rate contract, the tender conditions and the Quality Policy were duly accepted by Kemecos India Pvt. Ltd.. Hence the firm statement "Test Reports of your empanelled approved Laboratories are not admissible" is neither correct nor justifiable.
- (ii) For testing, samples of the said drug batches were sent to UPMSCL Empanelled laboratories. After the initial NSQ report, confirmatory testing samples were again

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sent to two other empanelled laboratories. On the basis of the laboratory reports provided by all three empanelled laboratories, the said 26 drug batches were finally declared "Not of Standard Quality".

- (iii) In the *Indian Pharmacopoeia* 2022, General Chapters, page 1300, it is clearly stated that: "During manufacture, packaging, storage and distribution of creams, suitable means shall be taken to ensure their microbial Quality". Acceptance criteria for the microbiological quality of non-sterile dosage forms are clearly specified in *Chapter 2.2.9 (Microbial Contamination in Non-Sterile Products)*, page 51, Table 5. Hence, the firm statement that limits for non-sterile products are not mentioned in the *Indian Pharmacopoeia* is incorrect. It is important to mention here that the acceptance criteria for TAC is 10^2 ; however, during testing, it was found to be *too numerous to count*, which is an alarming indication of the product's quality. On this basis of three laboratories report, the 26 drug batches were declared *Not of Standard Quality*.
- (iv) As the drug batches have been declared *Not of Standard Quality* by UPMSCL-empanelled laboratories, action shall be taken as per the tender conditions accepted by Kemecos India Pvt. Ltd. at the time of the agreement. Furthermore, as per the guidelines issued by The Central Drugs Standard Control Organisation (CDSCO) issued guidelines to the State Drug Controllers for taking action on samples of drugs declared spurious or *Not of Standard Quality* in light of the enhanced penalties under the *Drugs and Cosmetics (Amendment) Act, 2008*, the drug batches fall under the NSQ Category A due to fungal growth, and the information has also been sent to the Drug Controlling and Licensing Authority, UPFSDA, for further actions in accordance with the guidelines.
- (v) In the *Indian Pharmacopoeia* 2022, Acceptance criteria for the microbiological quality of non-sterile dosage forms are clearly specified in *Chapter 2.2.9 (Microbial Contamination in Non-Sterile Products)*, page 51, Table 5. Hence, the firm statement that limits for non-sterile products are not mentioned in the *Indian Pharmacopoeia* is incorrect. It is important to mention here that the acceptance criteria for TAC is 10^2 ; however, during testing, it was found to be *too numerous to count*, which is an alarming indication of the product's quality. On this basis, the said drug batches were declared *Not of Standard Quality*.

Till date, 26 drug batches of drug "Benzyl Benzoate Application: 25% w/w (-) 100 ml Bottle" were declared "Not of Standard Quality" (All 26 drug batches were declared "Not of Standard Quality" from UPMSCL empanelled Laboratories. Test reports of Twenty six "Not of Standard Quality" drug batches have neither been cancelled nor annulled by any higher authority and therefore, the report provided by UPMSCL empanelled Laboratories remains conclusive report till date.

Firm's representation dated 21.07.25 and 06.08.2025 were taken in to consideration but not found correct and justifiable with reference to tender conditions. Hence due to violation of tender conditions, Following has been implemented :

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- (A) Due to violation of Tender Condition No. 11 (v), Quantity corresponding to twenty six NSQ drug batches shall be deemed as non-supply and flat 20% penalty shall be levied on the value of corresponding quantity.
- (B) As per tender condition 11 (vii), Firm has not done recall of twenty six "Not of Standard Quality" declared drug batches within 30 days of receipt of notice dated 16.07.2025 hence after 30 days, 0.2% demurrage shall be levied on the value of corresponding quantity lying at District Drug warehouses and In case the Firm does not take back the stock of Twenty NSQ drugs back within 90 days of intimation, then UPMSCL shall be at liberty to destroy the quantity lying at warehouses. Supplier shall be liable to pay the expenses incurred for such destruction in addition to the demurrage charges applicable.

Apart from above, Firm Kemecos India Private Limited has also violated the tender (UPMSCL/Drug-208/52 dated-08.03.2024) 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 the period of 03 (Three) Years] by supplying Twenty six "Not of Standard Quality" drug batches (Batch no. BB-791, BB-793, BB-794, BB-795, BB-796, BB-798, BB-799, BB-802, BB-803, BB-804, BB-810, BB-811, BB-812, BB-816, BB-817, BB-818, BB-826, BB-833, BB-837, BB-838 , BB-843, BB-845, BB-853, BB-863, BB-864 and BB-865 of drug "Benzyl Benzoate Application: 25% w/w (-) 100 ml Bottle" to different District Drug warehouses of Uttar Pradesh Medical Supplies Corporation Ltd.

Hence, Firm Kemecos India Private Limited is, hereby, blacklisted for the drug "Benzyl Benzoate Application: 25% w/w (-) 100 ml Bottle" for three years from the date of issue of this order.

Enclosure : As above.

Managing Director
UPMSCL

Endorsement No.: UPMSCL/MD/QC/2025/ **Dated :** - Aug- 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.
2. Drug Licensing & Controlling Authority, UP, Office of Commissioner, Food Safety & Drug Administration, Sector-C, Aliganj, Lucknow.
3. Senior Consultant, UPMSCL.
4. Consultant, Drug Procurement, UPMSCL.
5. General Manager, Quality Control, UPMSCL.
6. General Manager, Drugs Procurement, UPMSCL.
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9. Manager, Quality Control, UPMSCL.
10. Manager, IT, UPMSCL.
11. Project Manager, DVDMS, UPMSCL.
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