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

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 laboratotries 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 :

(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.
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. Warehouse Pharmacist, All District Drug Warehouses of UPMSCL
13. M/S Kemecos India Private Limited126, B.B. Chatterjee Road, Kasba, Kolkata - 700042

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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.
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3. Senior Consultant, UPMSCL.
4. Consultant, Drug Procurement, UPMSCL.
5. General Manager, Quality Control, UPMSCL.
6. General Manager, Drugs Procurement, UPMSCL.
7. General Manager, Supply Chain, UPMSCL.
8. Manager, Legal, UPMSCL.

9. Manager, Quality Control, UPMSCL.
10. Manager, IT, UPMSCL.
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12. Warehouse Pharmacist, All District Drug Warehouses of UPMSCL
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Managing Director
UPMSCL

Uttar Pradesh Medical Supplies Corporation Limited

(A Govt. of Uttar Pradesh Undertaking)
GSTIN: 09AACCU2250P1ZZ CIN: U85310UP2018SGC102425
Registered Office : SUDA Bhawan, 7/23, Sector-7, Gomti Nagar Extension, Lucknow-226002
Website: www.upmsc.in Contact Number: 0522-2838102

Ref.No. UPMSCL/05/2025-26/1512 **Dated :** 29January-2026

ORDER

To,

Kemecos India Private Limited
126, BB Chatterjee Road, P.S. Kasba,
Kolkata, West Bengal 700042

Kemecos India Private Limited participated in the tender and after being declared successful the Company entered into the rate contract with Uttar Pradesh Medical Supplies Corporation Ltd. (UPMSCL) for supply of drug "Benzyl Benzonate Application: 25% w/w (-) 100 ml Bottle.

Pursuant thereto drugs were supplied by the Company to various District Drug Warehouses of Uttar Pradesh Medical Supplies Corporation Ltd. In the aforesaid supply made by the company various Drug Batches were declared "Not of Standard Quality" from UPMSCL empanelled Laboratories. Thus Notice Ref No. UPMSCL/MD/QC/2025/490 dated 16.07.2025 was sent to the Company. The Company has sent its reply/response vide letter no. KIPL/118/25-26 dated 21.07.2025 through email dated 21.07.2025 followed by courier on 29.07.2025. The Company has also sent the letter dated 06.08.2025. After considering the written reply of the Company the order dated 26.08.2025 (Ref.No.UPMSCL/MD/QC/2025/724) was issued to the Firm Kemecos India Private Limited.

The company challenged the order dated 26.08.2025 before the Hon'ble High Court at Calcutta by filing WPA No. 21809 of 2025 *re: Kemecos India Private Limited & Anr. Vs. Uttar Pradesh Medical Supplies Corporation Limited & Anr* . Hon'ble High Court vide order dated 26.09.2025 disposed of the petition with following observations:

1. *Learned advocate, appearing on behalf of the respondent submits, upon instructions that as oral opportunity was admittedly, not granted to the petitioners prior to passing the order of blacklisting, accordingly, the authority is agreeable to grant an opportunity of oral hearing to the petitioners*
2. *The court appreciates the fair stand taken by the respondent authority..*
3. *To comply with the principles of natural justice and opportunity of hearing ought to be given to the petitioners.*
4. *The instant writ petition, accordingly, stands disposed of by directing the respondents to afford an opportunity of hearing to rep petitioner and thereafter take a decision in the matter.*
5. *The impugned order of blacklisting dated 26th August 2025, and any consequential steps taken thereafter shall be kept in abidance till a fresh decision is taken by the Authority.*
6. *The writ petition stands disposed of In compliance of the order dated 26.09.2025 passed by the Hon'ble High Court At Calcutta the order no. UPMSCL/MD/QC/2025/724 dated 26.08.2025 was kept*

on abeyance and the Company was directed vide letter dated 30.10.2025 to appear before the Managing Director, UPMSCL, Lucknow on 10.11.2025 at 12:00 PM for oral submission in the matter.

On 10.11.2025 Director of the Company Sri Tapan Ghosh appeared along with Sri Atri Dasgupta, Executive, Sri Ushananda Jana, Advocate and Sri Sujit Bhattacharya Advocate before the Managing Director, UPMSCL, Lucknow.

The director of the company and its representatives were orally heard and opportunity was given to them to place their objections and submissions. They were also given opportunity to submit the written submissions if they so chooses. The Company filed the written representation along with documents and relevant extracts of Drug and Cosmetics Act and IP 2022.

I have perused the records, oral submissions and written representation submitted by Kemecos India Private Limited in the light of the relevant provisions of Drug and Cosmetics Act, 1940 and Indian Pharmacopeia.

Kemecos India Private Limited has supplied drug "Benzyl Benzoate Application: 25% w/w (-) 100 ml Bottle to various warehouses of the UPMSCL in various batches. After the supply of drug to various warehouses test were conducted by UPMSCL through its approved laboratories as per the tender condition no. 11 of tender no UPMSCL/Drug-208/52 dated-08.03.2024, which provides that *"Confirmatory quality testing of supplied drug batches shall be as per the UPMSCL Quality Policy."* The Quality Policy of UPMSCL in Clause 3 (ii) provides "Sample of all batches of all drugs (Unless Exempted) & identified medical consumables received through UPMSCL Central procurement shall be subjected to physical verification for tender condition, statutory compliance & confirmatory quality testing at NABL accredited drug, testing, laboratories empanelled by UMPSCL/Govt. laboratories before distributing the drug to facility level. Till the time any drug batch (unless exempted) is declared of "Standard Quality" based on empanel lab, analytical test report, drug batch, which is sent for testing shall be kept on hold as "Quarantine stock" and shall not be distributed to health facilities.

After supply the drug batches under various purchase orders were tested for confirmatory quality testing.

S. no	Mfg date & Exp. Date	Batch No	Lab Name	Report no	Report Date	Test result status	Reason for NSQ	Microbial count	Final Test Result
1.	01/2025 12/202	BB-791	Shree Balaji Test Lab Pvt. Ltd.	SBTLF-240325083	03-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count"	TAC=TNTC TFC=<10 cfu/gm	NSQ
			Sophisticated	FT05170019	30-05-	NSQ	Does not	TAC=5650	

	6		industrial materials analytic labs pvt. Ltd	25	2025		comply w.r.t "Microbiological Examination "	cfu/gm TFC=945 cfu/gm	
			ITL Labs Pvt. Ltd	D2025051301060	12-06-2025	NSQ	Does not comply w.r.t "Microbial Contamination"	TAC=250cfu/gm TFC=<10 cfu/gm	
2.	01/2025 12/2026	BB-793	Sophisticated Industrial Materials Analytic labs Pvt. Ltd	FT0310008925	27-03-2025	NSQ	Does not comply w.r.t "Total Bacterial Count & Total Fungal Count"	TAC=3750cfu/gm TFC=1120 cfu/gm	NSQ
			Shree Balaji Test Lab Pvt. Ltd	SBTLF-290425021	21-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count"	TAC=TNTC TFC=<10 cfu/gm	
			ITL Labs Pvt. Ltd.	D2025042600570	26-06-2025	NSQ	Does not comply w.r.t "Microbial Contamination"	TAC=260cfu/gm TFC=<10 cfu/gm	
3.	01/2025 12/2026	BB-794	Sophisticated Industrial Materials Analytic labs Pvt. Ltd	FT0310008825	27-03-2025	NSQ	Does not comply w.r.t "Total Bacterial Count & Total Fungal Count"	TAC=73000 cfu/gm TFC=9900 cfu/gm	NSQ
			Shree Balaji Test Lab Pvt. Ltd.	SBTLF-290425020	21-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count and P.aeruginosa "	TAC=TNTCcfu/gm TFC=<10 cfu/gm	
			ITL Labs Pvt. Ltd.	D2025042600600	26-06-2025	NSQ	Does not comply w.r.t "Microbial Contamination"	TAC=470 cfu/gm TFC=<10 cfu/gm	
4.	01/2025 12/2026	BB-795	Shree Balaji Test Lab Pvt. Ltd.	SBTLF-170325055	02-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count"	TAC=282 cfu/gm TFC=<10 cfu/gm	NSQ
			Sophisticated Industrial	FT0517001825	30-05-2025	NSQ	Does not comply w.r.t	TFC=1095cfu/gm	

			Materials Analytic labs Pvt. Ltd				"Total Bacterial Count & Total Fungal Count"	TFC=710 cfu/gm	
			ITL Labs Pvt. Ltd.	D2025051301080	09-06-2025	SQ	Standard Quality	TAC=90 cfu/gm TFC=<10 cfu/gm	
5.	01/2025 12/2026	BB-796	Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT0310008725	27-03-2025	NSQ	Does not comply w.r.t "Total Bacterial Count & Total Fungal Count."	TAC=8800cfu/gm TFC= 3250 cfu/gm	NSQ
			Shree Balaji Test Lab Pvt. Ltd.	SBTLF-290425025	21-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count and P.aeruginosa "	TAC=TNTC TFC=<10 cfu/gm	
			ITL Labs Pvt. Ltd.	D2025042600620	26-06-2025	NSQ	Does not comply w.r.t "Microbial Contamination"	TAC=375 cfu/gm TFC=<10 cfu/gm	
6.	01/2025 12/2026	BB-798	Sophisticated Industrial Materials Analytic labs Pvt. Ltd	FT0306009525	19-03-2025	NSQ	Does not comply w.r.t "Total Bacterial Count & Total Fungal Count"	TAC=87500 cfu/gm TFC=795 cfu/gm	NSQ
			Shree Balaji Test Lab Pvt Ltd.	SBTLF-290425024	21-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count and P.aeruginosa "	TAC=TNTC TFC=<10 cfu/gm	
			ITL Labs Pvt. Ltd.	D2025042600610	26-06-2025	NSQ	Does not comply w.r.t "Microbial Contamination"	TAC=420 cfu/gm TFC=<10 cfu/gm	
7.	01/2025 12/202	BB-799	Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT0310008625	27-03-2025	NSQ	Does not comply w.r.t "Total Bacterial Count & Total Fungal	TAC=10000 cfu/gm TFC=18500 cfu/gm	NSQ

	6						Count"		
			Shree Balaji Test Lab Pvt Ltd.	SBTLF-290425022	21-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count and P.aeruginosa "	TAC=TNTC TFC=<10 cfu/gm	
			ITL Labs Pvt. Ltd.	D2025042600630	26-06-2025	NSQ	Does not comply w.r.t "Microbial Contamination"	TAC=665 cfu/gm TFC=<10 cfu/gm	
8.	01/2025 12/2026	BB-802	Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT0322005825	03-04-2025	NSQ	Does not comply w.r.t "Total Bacterial Count & Total Fungal Count"	TAC=34000 cfu/gm TFC=6050 cfu/gm	NSQ
			ITL Labs Pvt. Ltd	D2025042600650	26-06-2025	NSQ	Does not comply w.r.t "Microbial Contamination"	TAC=430 cfu/gm TFC=<10 cfu/gm	
			Shree Balaji Test Lab Pvt Ltd.	SBTLF-290425160	21-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count and P. aeruginosa"	TAC=TNTC TFC=<10 cfu/gm	
9.	01/2025 12/2026	BB-803	Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT0312007225	27-03-2025	NSQ	Does not comply w.r.t "Total Bacterial Count & Total Fungal Count"	TAC=170500 cfu/gm TFC=62000 cfu/gm	NSQ
			Shree Balaji Test Lab Pvt Ltd.	SBTLF-290425023	21-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count and P.aeruginosa ."	TAC=TNTC TFC=<10 cfu/gm	
			ITL Labs Pvt. Ltd.	D2025042600660	26-06-2025	NSQ	Does not comply w.r.t "Microbial Contamination"	TAC=515 cfu/gm TFC=<10 cfu/gm	
10.	01/202	BB-804	Sophisticated Industrial	FT0303011625	19-03-2025	NSQ	Does not comply w.r.t	TAC=2550 cfu/gm	NSQ

	5 12/ 202 6		Materials Analytic Labs Pvt. Ltd				"Total Bacterial Count & Total Fungal Count"	TFC=10600 cfu/gm	
			Shree Balaji Test Lab Pvt Ltd.	SBTLF-290425153	21-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count and P.aeruginosa "	TAC=TNTC TFC=<10 cfu/gm	
			ITL Labs Pvt. Ltd.	D2025042600590	26-06-2025	NSQ	Does not comply w.r.t "Microbial Contamination"	TAC=600 cfu/gm TFC=<10 cfu/gm	
11.	01/ 202 5 12/ 202 6	BB-810	Shree Balaji Test Lab Pvt. Ltd.	SBTLF-270325111	03-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count"	TAC=TNTC TFC=<10 cfu/gm	NSQ
			Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT0514004725	27-05-2025	NSQ	Does not comply w.r.t " Total aerobic viable count"	TAC=6850000 cfu/gm TFC=34000 cfu/gm	
			ITL Labs Pvt. Ltd.	D2025051000030	03-06-2025	NSQ	Does not comply w.r.t "Microbial Contamination"	TAC=more than 100 cfu/gm TFC=more than 10 cfu/gm	
12.	01/ 202 5 12/ 202 6	BB-811	Shree Balaji Test Lab Pvt Ltd.	SBTLF-270325091	02-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count	TAC=TNTC TFC=<10 cfu/gm	NSQ
			ITL Labs Pvt. Ltd	D2025051000020	03-06-2025	NSQ	Does not comply w.r.t "Microbial Contamination	TAC=more than 100 cfu/gm TFC=more than 10 cfu/gm	
			Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT0514004825	23-05-2025	NSQ	Does not comply w.r.t "Microbial Examination Total Bacterial Count.	TAC=3350 cfu/gm TFC=<10 cfu/gm	
13.	01/ 202	BB-812	Shree Balaji Test Lab Pvt Ltd.	SBTLF-080425105	21-05-2025	NSQ	Does not comply w.r.t	TAC=TNTC TFC=<10	NSQ

	5 12/ 202 6						"Total Bacterial Count & Total Fungal Count.	cfu/gm	
			Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT06030039 25	16-06-2025	NSQ	Does not comply w.r.t "Total Bacterial Count & Total Fungal Count.	TAC=272000 cfu/gm TFC=250 cfu/gm	
			ITL Labs Pvt. Ltd	D202505310 056O	18-06-2025	NSQ	Does not comply w.r.t "Microbial Contaminati on	TAC=220 cfu/gm TFC=<10 cfu/gm	
14.	02/ 202 5 01/ 202 7	BB-816	Shree Balaji Test Lab Pvt. Ltd.	SBTLF-120425129	15-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count"	TAC=TNTC TFC=<10 cfu/gm	NSQ
			Sophisticated Industrial Materials Analytical Lab (SIMA LABS)	FT05300019 25	13-06-2025	NSQ	Does not comply w.r.t "Total Bacterial Count "	TAC=11650 cfu/gm TFC=<10 cfu/gm	
			ITL Labs Pvt. Ltd	D202506110 0094O	03-07-2025	SQ	Standard Quality	TAC=<10 cfu/gm TFC=<10 cfu/gm	
15.	02/ 202 5 01/ 202 7	BB-817	Shree Balaji Test Lab Pvt Ltd.	SBTLF-120425127	15-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count"	TAC=TNTC TFC=<10 cfu/gm	NSQ
			Sophisticated Industrial Materials Analytical Lab (SIMA LABS)	FT05300018 25	11-06-2025	NSQ	Does not comply w.r.t "Total Bacterial Count "	TAC=3450 cfu/gm TFC=760 cfu/gm	
			ITL Labs Pvt. Ltd	D202506110 095O	09-07-2025	SQ	Standard Quality	TAC=<10 cfu/gm TFC=<10 cfu/gm	
16.	02/ 202 5 01/ 202 7	BB-818	Shree Balaji Test Lab Pvt Ltd.	SBTLF-260325042	02-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count.	TAC=TNTC TFC=<10 cfu/gm	NSQ
			Sophisticated Industrial Materials Analytic	FT05140046 25	23-05-2025	NSQ	Does not comply w.r.t "Microbial	TAC=2500 cfu/gm TFC=<10	

			Labs Pvt. Ltd				Examination Total Bacterial Count.	cfu/gm	
			ITL Labs Pvt. Ltd	D2025051000040	03-06-2025	NSQ	Does not comply w.r.t "Microbial Contamination	TAC=more than 100 cfu/gm TFC= more than 10 cfu/gm	
17.	02/2025 01/2027	BB-826	Shree Balaji Test Lab Pvt Ltd.	SBTLF-020425014	02-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count.	TAC=TNTC TFC=<10 cfu/gm	NSQ
			Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT0514004525	23-05-2025	NSQ	Does not comply w.r.t "Microbial Examination Total Bacterial Count.	TAC=1020 cfu/gm TFC=<10 cfu/gm	
			ITL Labs Pvt. Ltd	D2025051000050	03-06-2025	NSQ	Does not comply w.r.t "Microbial Examination	TAC=more than 100 cfu/gm TFC= more than 10 cfu/gm	
18.	02/2025 01/2027	BB-833	Shree Balaji Test Lab Pvt Ltd.	SBTLF-070425048	21-05-2025	NSQ	Total aerobic viable count and P.aeruginosa "	TAC=TNTC TFC=<10 cfu/gm	NSQ
			ITL Labs Pvt. Ltd	D2025053100650	18-06-2025	SQ	Standard Quality	TAC=30 cfu/gm TFC=<10 cfu/gm	
			Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT0603005925	24-06-2025	NSQ	Does not comply w.r.t "Microbial Examination Total Bacterial Count.	TAC=282000 cfu/gm TFC=220 cfu/gm	
19.	02/2025 01/2027	BB-837	Shree Balaji Test Lab Pvt Ltd.	SBTLF-140425158	21-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count and P.aeruginosa .	TAC=TNTC TFC=<10 cfu/gm	NSQ
			ITL Labs Pvt. Ltd	D2025053100	18-06-	SQ	Standard	TAC=40	

				054O	2025		Quality	cfu/gm TFC=<10 cfu/gm	
			Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT06030037 25	17-06-2025	NSQ	Does not comply w.r.t "Microbial Examination Total Bacterial Count	TAC=600000 cfu/gm TFC=<10 cfu/gm	
20.	02/2025 01/2027	BB-838	Shree Balaji Test Lab Pvt Ltd.	SBTLF-120425130	15-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count	TAC=TNTC TFC=<10 cfu/gm	NSQ
			ITL Labs Pvt. Ltd	D202506110 087O	30-06-2025	SQ	Standard Quality	TAC=<10 cfu/gm TFC=<10 cfu/gm	
			Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT05300010 25	11-06-2025	NSQ	Does not comply w.r.t "Total Bacterial Count & Total Fungal Count.	TAC=3450 cfu/gm TFC=760 cfu/gm	
21.	02/2025 01/2027	BB-843	Shree Balaji Test Lab Pvt Ltd.	SBTLF-290425149	21-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count and P.aeruginosa .	TAC=TNTC TFC=<10 cfu/gm	NSQ
			Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT06030040 25	16-06-2025	NSQ	Does not comply w.r.t "Microbial Examination Total Bacterial Count	TAC=41500 cfu/gm TFC=4300 cfu/gm	
			ITL Labs Pvt. Ltd	D202505310 057O	18-06-2025	NSQ	Does not comply w.r.t "Microbial Contaminati on	TAC=320 cfu/gm TFC=<10 cfu/gm	
22.	02/2025 01/2027	BB-845	Shree Balaji Test Lab Pvt Ltd.	SBTLF-290425019	21-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count and P.aeruginosa .	TAC=TNTC TFC=<10 cfu/gm	NSQ
			Sophisticated		16-06-	NSQ	Does not	TAC=111500	

			Industrial Materials Analytic Labs Pvt. Ltd	FT0603003825	2025		comply w.r.t "Microbial Examination Total Bacterial Count	cfu/gm TFC=8000 cfu/gm	
			ITL Labs Pvt. Ltd	D2025053100600	18-06-2025	SQ	Standard Quality	TAC=90 cfu/gm TFC=<10 cfu/gm	
23.	02/2025 01/2027	BB-853	Shree Balaji Test Lab Pvt Ltd.	SBTLF-280425102	21-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count and P.aeruginosa.	TAC=TNTC TFC=<10 cfu/gm	NSQ
			Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT0603005725	16-06-2025	NSQ	Does not comply w.r.t "Microbial Examination Total Bacterial Count.	TAC=40000 cfu/gm TFC=8250 cfu/gm	
			ITL Labs Pvt. Ltd	D2025053100680	18-06-2025	SQ	Standard Quality	TAC=50 cfu/gm TFC=<10 cfu/gm	
24.	02/2025 01/2027	BB-863	Shree Balaji Test Lab Pvt Ltd.	SBTLF-120425097	15-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count"	TAC=TNTC TFC=<10 cfu/gm	NSQ
			Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT0530001725	11-06-2025	NSQ	Does not comply w.r.t "Total aerobic viable count"	TAC=3450 cfu/gm TFC=760 cfu/gm	
			ITL Labs Pvt. Ltd	D2025061100860	03-07-2025	SQ	Standard Quality	TAC=<10 cfu/gm TFC=<10 cfu/gm	
25.	02/2025 01/2027	BB-864	Shree Balaji Test Lab Pvt Ltd.	SBTLF-120425095	21-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count and P.aeruginosa.	TAC=TNTC TFC=<10 cfu/gm	NSQ
			Sophisticated Industrial Materials Analytic	FT0603005825	16-06-2025	NSQ	Does not comply w.r.t "Microbial Examination	TAC=25500 cfu/gm TFC=9850 cfu/gm	

			Labs Pvt. Ltd				Total Bacterial Count.		
			Itl Labs Pvt. Ltd	D2025053100630	18-06-2025	NSQ	Does not comply w.r.t "Microbial Contamination	TAC=165 cfu/gm TFC=<10 cfu/gm	
26.	02/2025 01/2027	BB-865	Shree Balaji Test Lab Pvt Ltd.	SBTLF-120425094	15-05-2025	NSQ	Does not comply w.r.t "Total aerobic viable count .	TAC=TNTC TFC=<10 cfu/gm	NSQ
			Sophisticated Industrial Materials Analytic Labs Pvt. Ltd	FT0530000825	11-06-2025	NSQ	Does not comply w.r.t "Total Bacterial Count & Total Fungal Count	TAC=3450 cfu/gm TFC=760 cfu/gm	
			Itl Labs Pvt. Ltd	D2025061100920	26-06-2025	SQ	Standard Quality	TAC=<10 cfu/gm TFC=<10 cfu/gm	

Based on the aforesaid results the Notice for supply of "Not of Standard Quality" 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, BB-865" to different District Drug warehouses of Uttar Pradesh Medical Supplies Corporation Ltd. was served upon the company along with the test reports.

The Company submitted the reply to the show cause notice vide letter no. KIPL/118/25-26 dated 21.07.2025 through email dated 21.07.2025 followed by courier on 29.07.2025.

On 10.11.2025 the company submitting the written representation in which following averments were made:

1. The Kemecos India Private Limited is a Micro Small and Medium Enterprises (MSME) engaged in manufacture and supply of drugs and medicines. It is a licensed manufacturer of Medicines.
2. The Kemecos India Private Limited was selected as successful bidder for supplying a drug, Benzyl Benzoate Application 25% w/w 100 ml bottle as per tender reference No. UPMSCL/Drugs-208/52 dated 08.08.2024 floated by Uttar Pradesh Medical Supplies Corporation Ltd.(UPMSCL) for the last three years. After duly execution of Letter of intent and Bank guarantee for performance security, Integrity Pact, the Kemecos India Private Limited supplied the said drug to the different warehoused of UPMSCL as per UPMSCL's order, after duly uploading in UPMSCL's Portal of Analytical test Report of NABL Accredited Laboratory. The Kemecos India Private Limited is required to supply Benzyl Benzoate Application with Analytical Test Report of approval Laboratory (NABL Accredited Laboratory). Accordingly Kemecos India Private Limited submitted Analytic Test Reports of

all supplied Batches of Benzyl Benzoate Application since 2022. The Test Reports of said drugs did not reflect Microbiological Tests for Total Aerobic Count (TAC), Total Fungal Court (TFC) and Specific organizations since Indian Pharmacopoeia, 2022 and its addendum 2024 does not prescribe Microbiological Test for Non sterile product used for cutaneous purpose.

3. That as petitioner's own Test Reports and approved laboratories (NABL Accredited) the Benzyl Benzoate application 25% W/W 100 ml bottle having alleged 26 Batches were found to be standard quality, wherein microbiological tests were not reflected and accordingly you have accepted the said alleged batches. Thereafter the petitioner supplied the said Batches and other batches to your different warehouses.
4. That Chapter IV of the Drugs and Cosmetics Act deals with the manufacture, sale and distribution of Drugs and Cosmetics. Section 16 of the Act governs the expression (Standard quality), whereas Sections 17, 17A and 17B govern misbranded, adulterated, and spurious drugs. You conducted a lab test from three different approved Laboratories (NABL Accredited) which suggests the sample of said drugs failed in respect of microbiological test. The test reports of you did not match the test reports supplied by the petitioner to you. Your Laboratories have fraudulently prepared test reports. The private approved laboratories do not have the legal standing and are generally not admissible as conclusive evidence in Court under Section 293 of Cr.P.C. UPMSCL were aware of the petitioner's performance in supplying Benzyl Benzoate application 25% W/W and UPMSCL was quite satisfactory regarding quality of the said products.
5. The Kemecos India Private Limited requested to disburse the payment dues at the tune of Rs.2,18,17,210.20 (Rupees Two Crores Eighteen Lakhs Seventeen Thousand Two hundred ten and twenty paise) only to UPMSCL resulting you had issued show cause letter dated 16.07.2025 along with Test Reports of UPMSCL's empanelled Laboratories by claiming that 26 Batches of Benzyl Benzoate Application 25% W/W 100 ml bottle were found to be not of standard quality on the ground of higher specificity and sensitivity in respect of Microbiological test as opined by the private Analyst of different empanelled Laboratories of UPMSCL. By the said show-cause notice Kemecos India Private Limited was asked to explain why the supplied quantity of 26 Batches of Benzyl Benzoate Application 25% W/W 100 ml bottle should not be treated as non supply and payment of corresponding value should not be deducted; to explain 20% of the above value should not be taken as penalty; 0.2% demurrage shall be levied; to explain why the petitioner no.1 should not be blacklisted. It is pertinent to mention here that Test Reports of your empanelled Laboratories did not highlight total aerobic count (TAC), Total Fungal Count (TFC) and specific organizations in their Test Reports since inception of Indian Pharmacopoeia - 2022. All of a sudden i.e. after March, 2025 they have started Microbiological Test for said drugs. Therefore their credibility is doubtful. All approved Laboratories are identical and same in terms of Rule 150-C of Drugs and Cosmetics Rules, 1945.
6. That you have removed the label from the bottle of Benzyl Benzoate application 25% W/W which was adhered by Kemecos India Limited and subsequently you have adhered another label wherein exact Batch No. and name of manufacturer were omitted and as such the

product must be opined as "Misbranded Drugs" in terms of Section 17(e) of the Drugs and Cosmetics Act. But the Test Reports in Form 39A of 26 Batchers of Benzyl Benzoate application 25% W/W did not reflect so and as such the status of said Test Reports are non-est in nature i.e. invalid, void or without legal effect. Therefore, your office order dated 26.08.2025 on the basis of said Test Reports issued by your empanelled approved Laboratories are non-est order, decision, or transaction is ineffective and carries no legal consequences because it is considered void from the beginning. Hence, non-est factum makes the contract void from the beginning (Void ab initio). It is fraud and misrepresentation on part of you in terms of Sections 17 and 18 of Indian Contact Act.

7. That an approved laboratory in Form 37 under Rule 150-C of Drugs and Cosmetics Rules, 1945 can carry out microbiology tests, provided the specific approval mentions "Microbiological tests and assays" or the relevant category of drugs requiring such tests in its scope. The approval also names the competent Technical staff, including microbiologist. To ascertain the presence of microbiologist in your empanelled laboratories, it needs to provide Form 37 of said laboratories who performed the microbiological tests as reflected in Form 39A. The said empanelled intuition did not furnish the Test Report in form 39A to the approving authority and licensing authority of the State of West Bengal in terms of rule 150E(G) of the Drugs and Cosmetics Rules, 1945.
8. The Licensing authority of the approved laboratories has the power under Rule 159 of the Drugs and Cosmetics Rules 1945 to suspend or cancel the licence of an approved laboratory. Since it fails to comply with the provisions of said Act and Rule. Approved laboratories have a duty to provide correct and accurate information. Breaches of this duty can lead to Legal action for negligence. Here individual analyst or person in charge can be held liable for their actions and tantamount to negligence, connivance, or a deliberate attempt to conceal damage or provide information.
9. The Kemecos India Private Limited submitted detailed written response on 21.07.2025 clarifying that standard quality of Benzyl Benzoate Application 25%w/w 100 ml bottle were supplied since active ingredient of the said formulation is within limit as revealed from Analytical Test Reports. Moreover there is no objection/complaint since 2022 regarding public safety. The supplied drug is under the perview of Drugs and Cosmetic Act, 1940 and Rules thereunder. The said drug was not tested by Govt. analyst of Central Drugs Laboratory, Kolkata. The incorporation of microbiological test is the novation of the Tender clauses. Therefore the dispute regarding not of standard quality does not arise at all. The dispute regarding quality of the alleged drug is not arbitrable since Drugs and Cosmetics Act, is not a civil Act. You have failed to discharge your obligation as per tender clause 14 regarding payment terms i.e. within 45 days of completion of supply based on quality clearance status.
10. That you have issued office order dated 26.08.2025 declaring that (i) quantity corresponding to 26 batches of Benzyl Benzoate Application 25% w/w 100 ml bottle are not of standard, shall be deemed as non-supply and (ii) flat 20% penalty shall be levied on the value of the corresponding quantity (iii) 0.2% demurrage (iv) the petitioner has been blacklisted for 3 years for the Drug Benzyl Benzoate Aplication 25% w/w/ 100 ml bottle, costing will be

imposed for destruction of 26 batches of Benzyl Benzoate Application 25% w/w 100 ml bottle.

11. The issuance of office order dated 26.08.2025 is vitiated for non-compliance of Section 25(3)(4) of the Drugs and Cosmetics Act. You are required to complete the formality as per provisions of the Drugs and Cosmetics Act, thereafter, you ought to be taken necessary steps as per provisions of the Drugs and Cosmetics Act. But you did not comply with provisions of Drugs and Cosmetics Act. Therefore, the valuable right of the petitioner has been infringed.
12. The test reports in Form 39A of alleged 26 batches of Benzyl Benzoate Application 25% W/W 100 ml bottle bears the name of the sample as Benzyl Benzoate Application I.P. 25% W/W 100 ml bottle which is not at par with Schedule of requirement of e-tender in Serial No. 39 which reads as Benzyl Benzoate Application 25% W/W 100 ml bottle. Therefore, standards as prescribed in Indian Pharmacopoeia, 2022 are not applicable at all. The Monograph of Benzyl Benzoate Application of Indian Pharmacopoeia does not prescribe the provisions of microbiological test. The general chapter of I.P. 2022 provides microbiological test for non-sterile products. Surprisingly, there is no specification of total aerobic count and total fungal count and specific organisms for non-sterile product having cutaneous use. Therefore, the entire show cause notice is vitiated and not maintainable.
13. The test reports of your empanelled Laboratories did not bear the signature of Govt. Analyst and as such there is no evidence of the facts stated therein. The intention to adduce evidence in controversion of the report was not invited by you. Therefore, the office order dated 26.08.2025 is not sustainable in law.
14. The authority of UPMSCL attempted unilaterally to modify the terms of contract since tender clause did not claim/prescribe I.P. product. Therefore, specification of Benzyl Benzoate Application 25% W/W is at par with in-house specification of Kemecos India Private Limited.
15. Test Reports in Form 39A issued by the Private Analysts of empanelled laboratories on behalf of UPMSCL have not reached finality according to sub-rule (f) of Rule 150(E) of Drugs and Cosmetics Rules, 1945.
16. The tender clauses are not applicable for the drug Benzyl Benzoate Application 25% W/W 100 ml bottle since it is a drug as per Section 3(b) of the Drugs and Cosmetics Act, 1940 and it is under the ambit of said Act. Mere tender clauses are null and void. Hence, the question of not of standard quality in terms of Indian Pharmacopoeia 2022 does not arise at all.
17. Test Reports in Form 39A of your empanelled NABL Accredited Approved Laboratories are lacking the attributes as laid down in Clause (6) of said Form 39-A under sub-Rule (f) of Rule 150E of Drugs and Cosmetics Rules, 1945. It is mandatory and required to be complied with provisions of statute. This means otherwise statutes of the Drugs and Cosmetics Act and Rules thereunder provide to act in a way which was not done definitely here. Reference may be given in a very old judgment reported in Nazir Ahmed Vs. King Emperor, AIR 1936 P.C. 253 and in that judgment the principle applied in Taylor Vs. Taylor, (1874) Ch D 426. Where a power is given to do a certain thing must be done in that way and other methods of performance are necessary forbidden.

18. That the alleged drugs were supplied to different District Drug Warehouses of Uttar Pradesh Medical Supplies Corporation Limited as per tender No. UPMSCL/Drug-208/52 dated 08.03.2024 on the basis of acceptance of Test Report furnished on behalf of the petitioner by the approved laboratory (NABL Accredited) wherein microbial contaminations were not reflected on account of absence of acceptance criteria for microbiological quality of non-sterile substances for pharmaceutical use having route of cutaneous use. Here non-sterile substances are genus whereas cutaneous preparations are species. A court typically will not allow you to withdraw your acceptance of said Test Reports submitted by the petitioner. The principle is based on the ...idea that you cannot take contradictory positions and accepting benefits signifies a final decision for payment of dues of alleged drugs. The said Test Reports are lying in your portal.
19. That it is pertinent to mention here that you did not raise any objection regarding absence of Microbiological Test in respect of microbial contamination in non-sterile product for cutaneous purpose for the last three years for the alleged drugs. There is no complaint regarding public safety on account of non-adherence of microbiological test for the last three years as per provisions as laid down in Indian Pharmacopoeia, 2022.
20. That Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 are special law dealing with the regulation of drugs and cosmetics while Indian Contract Act is a general law governing contracts. The Drugs and Cosmetics Act supplements the Indian Contract Act in specific situations related to the sale and purchase of drugs and cosmetics. Drugs and Cosmetics Act adds specific provisions and regulations for contracts involving drugs and cosmetics, ensuring public safety and quality standards. The Drugs and Cosmetics Act also includes provisions related to licensing, manufacture and distribution of Drugs and Cosmetics which are not covered by the Indian Contract Act, 1872. If a contract involves the sale of drugs or cosmetics both the Indian Contract Act, and the Drugs and Cosmetics Act would be relevant.
21. That Drug Inspectors play crucial role in sampling of drugs in terms of Section 23 of the Drugs and Cosmetics Act, read with Rule 51 of Drugs and Cosmetics Rules, 1945; sending one part of sample to the Government Analyst appointed under Section 20 of said Act. The Government Analyst shall deliver Test Report i.e., results of test or analysis in Form-13 to the Inspector of Drugs within 60 days as per Rule 45 of Drugs and Cosmetics Rules, 1945. But here Inspector of Drugs did not draw samples as well as Government Analyst did not test or do analysis. Hence test reports of Approved Laboratories as empanelled by the respondents are null and void and the said test reports annexing with show cause notice have no legal effect. Inspector of Drugs are responsible for taking appropriate action based on the results in terms of Section 32 of the Drugs and Cosmetics Act. You have no locus standi to do so. Only the Licensing Authority of State of West Bengal is entitled to issue show cause notice in terms of Rule 85 of the Drug and Cosmetics Rules in case of not of standard quality of Drugs.
22. That Central Drugs Standard Control Organisation (CDSCO) issued Guidelines for taking action on samples of Drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008 whereby it is categorically mentioned that in the case of not of standard quality reports because of minor

defects arising out of variation from the prescribed standards or contraventions of other provisions of Chapter IV of the Act, administrative measure including suspension/cancellation or compounding of offences may be resorted to. Prosecution may only be launched where it is justifiably felt that above measures would not meet the ends of justice. But you did not follow the said guidelines, the reasons are best known to you.

23. That the valuable right of the Kemecos India Private Limited to challenge the report of the approved Laboratories could not be excised in terms of section 25(3), 25(4) of the said Act and consequently the show-cause notice dated 16.07.2025 is null and void.
24. That the moot question is whether the analyst of approved Laboratories had kept alleged Drugs as per storage condition Labelled on the foil and cartons inter alia Schedule – P of the Drugs and Cosmetics Rules, 1945?
25. That the fundamental right under Article 19(1)(g) of the Indian Constitution is guaranteed. Blacklisting, which prevents a company from participating in future tender or contracts, can effectively curtail its ability to operate in the pharmaceutical sector. However, such restrictions are not permissible arbitrarily and unfairly and without following the provisions as envisaged in Drugs and Cosmetics Act and Rules framed thereunder.
26. It is pertinent to note that the test reports of your empanelled laboratory namely Sima Labs Sophisticated Industrial Materials Analytic Labs Pvt. Ltd. mentioned I.P. 2022 page No. 1609 in their test reports in Form 39A but the monograph of Benzyl Benzoate Application does not prescribe Microbiological Test. The General chapter of Indian Pharmacopoeia Addendum, 2024 (page No. 51) does not prescribe any specifications for Total Aerobic Count (TAC) and Total Fungal Count (TFC) and Specific Organisms for non-sterile dosage forms having route of administration of cutaneous use. It is pertinent to note that Benzyl Benzoate application 25% W/W is for cutaneous use.
27. The Test Reports of your empanelled approved Laboratories are not admissible under Section 45 of Indian Evidence Act, 1872 corresponding to Section 39(1) of the Bharatiya Sakshya Adhiniyam, 2023.
28. That under Article 298 of Constitution the executive power of the Union and the State shall extend the making of contract for any purpose. The exercise of such powers and functions in trade by the State is subject to Part–III of the Constitution. Article 14 speaks of equality before the law and equal protection of the laws. The State or its instrumentality has the duty to observe equality. An ordinary individual can choose not to deal with any person. The government can not choose to exclude persons by discrimination. The order of blacklisting has the effect of depriving a person of equality of opportunity in the matter of public contract. A person who is on the approved list is unable to enter into advantageous relations with the Government because of the order of blacklisting. A person who has been dealing with the Government in the matter of sale and purchase of drugs has a legitimate interest or expectation. When the State acts to the prejudice of a person it has to be supported by legality.
29. That the blacklisting order does not pertain to any particular contract. The blacklisting order involves civil consequences. It casts a slur. It creates a barrier between the persons

blacklisted and the Government in the matter of transactions. The blacklists are "instruments of coercion".

30. On 26.09.2025 the Hon'ble High Court at Calcutta was pleased to dispose of writ petition being W.P.A No. 21809 of 2025 wherein "the impugned order of blacklisting dated 26th August, 2025 and any consequential steps taken thereafter shall be kept in abeyance till a fresh decision is taken by authority."
31. On 27.09.2025 the Kemecos India Private Limited requested you for disbursement of payments of Rs.1,41,90,800.88 (Rupees One Crore, forty one Lakhs Ninety thousand eight hundred and paise eighty eight only) against purchase order Nos. UP/UP/HQ/24/2128/1 (10282409644), UP/UP/HQ/24/2257/1 (10282410369), UP/UP/HQ 25/149/1 (10282500345), UP/UP/HQ/25/290/1(10282501150), UP/UP/HQ/25/351/1 (10282501554) and UP/UP/HQ/25/561/1 (10282502635) vide tender reference No. UPMSCL/Drugs-208/52 dated 08.08.2024 for compliance with solemn order passed by the Hon'ble High Court at Calcutta on 26.09.2025 in W.P.A. No. 21809 of 2025. But you did not disburse the said amount. It is pertinent to note that you have half-heartedly complied with said solemn order by selecting Kemecos India Private Limited as one of the eligible bidders in subsequent tender floated nationally by you.
32. That Inspector of Drugs will send Test Reports to the State Licensing Authority for taking necessary action as per Rule 85 of the Drugs and Cosmetics Rules or take legal action subject to the approval of Controlling Authority under Rule 50 of the Drugs and Cosmetics Rules, 1945. The Drugs and Cosmetics (Amendment) Act, 2008 passed by the Parliament on 5th December, 2008 provides deterrent penalties for offences relating to manufacture of spurious or adulterated drugs which have serious implications on public health. Here, the alleged product is not adulterated or spurious, even it has no implications on public health as revealed from use of said alleged products for the last three years in the State of Uttar Pradesh. The Legal/administrative action required under the Act and Rules for the violations of the provisions of the Act are known by the State Licensing Authority. The actions are normally initiated on the basis of test reports of Government Analysts declaring the drugs samples as "Not of Standard quality"
33. That the Central Drugs Standard Control Organisation (CDSCO) issued Guidelines for taking action on samples of Drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008 whereby it is categorically mentioned that in the case of not of standard quality reports because of minor defects arising out of variation from the prescribed standards or contraventions of other provisions of Chapter IV of the Act, administrative measures including suspension/cancellation or compounding of offences may be resorted to. Prosecution may only be launched where it is justifiably felt that above measures would not meet the ends of justice. But this guideline was not followed.
34. That the actions of you are irresponsible especially while the samples were not drawn by the Inspector of Drugs and the alleged drugs were not tested at the Central Drugs Laboratory, Kolkata. Hence, it is too early to reach any definite conclusions like the alleged drug is not of standard quality.

35. That the office order dated 26.08.2025 is totally contrary to the Drugs and Cosmetics Act, 1940 and Rules thereunder.
36. That the chain of events and the facts revocable from the conduct of the respondents clearly point at an after thought, motivated an arbitrary action of the respondents which do not stand the test of Article 14 of the Constitution of India. The respondent authorities have acted in the manner which relies all senses of proportionality and reasoning. Admittedly, the respondents have utilized Benzyl Benzoate application 25% W/W 100 ml bottle supplied for the purpose and that too only at a belated stage when payment for supply was demanded.
37. That show cause notice dated 16.07.2025 does not disclose the exact Batch No. given by the petitioner No. 1 on the Test Reports in terms of Rule 96 of the Drugs and Cosmetics Rules, 1945 and as such the test reports of empanelled Laboratories of respondents are non-est in nature. The respondents have now decided to raise allegations against the petitioners, by way of afterthought, only to delay the process of payment and to stop participating in the ensuring e-Tender for the supply of Drugs Benzyl Benzoate application I.P. 25% W/W 100 ml bottle to the respondent.
38. That e-tender clause did not prescribe abbreviated term of I.P. in terms of Rule 104 of the Drugs and Cosmetics Rules, 1945. Therefore, standards as laid down in I.P. (Indian Pharmacopoeia, 2022) does not applicable for Benzyl Benzoate application 25% W/W 100 ml bottle.
39. That the petitioners have not received one single complaint from any corner regarding the quality of Benzyl Benzoate application I.P. 25% W/W 100 ml bottle for nearly 3 years. Until March, 2025, you were clearly satisfied with the quality of the alleged said drugs and raised no whisper of any objection. It was only after the petitioner requested you to perform your obligation to make payment, the respondent authorities handed over Test reports of 'not of standard quality' of the drugs supplied. After having received the lion's share of the Drugs in December, 2024, to April, 2025 and clearly using and utilizing the same for several months, the respondents have now decided to raise allegations against the petitioners by way of afterthought, only to delay the process of payment.
40. That you are bound by a contract to fulfil your reciprocal obligations for the release of the payment due to the petitioner against the drugs which have been admitted supplied by the petitioner and duly accepted by you.
41. That the activities of you are violative of Articles 14, 19(1)(g), and 300A of the Constitution of India.
42. That in cases of variation between test reports of different approved Laboratories, the Law relies on the provision for re-testing by the Central Drugs Laboratory (CDL), Kolkata whose report is considered conclusive evidence under the Drugs and Cosmetics Act, 1940. Rule 150C and 150D pertains to the approval and duration of licences in Form 37 for Laboratories, not directly to the legal procedure for handling conflicting test results in a prosecution case. The relevant legal framework for addressing conflicting test reports is found in Section 25 of the Drugs and Cosmetics Act, 1940.
43. Various High Courts and Supreme Court have consistently upheld the statutory right to get the sample retested by the CDL and the conclusive nature of CDL's report. Courts have

emphasized that this right to re-testing must be exercised within stipulated 28-day period; failure to do so often results in the initial Government analyst's report being accepted as final. Significant unexplained delays by drug authorities in testing samples can invalidate proceedings under the Act, a point highlighted in several Supreme Court Judgements. The CDL's report indicates the drug is of standard quality, it effectively quashes the prosecution proceedings initiated based on the earlier adverse report. In essence, the legal resolution for variations in test reports is a revaluation by the designated national statutory laboratory (CDL), whose findings are legally binding. But here you did not do so. Hence you are bound to pay the amount of Rs. 1,41,90,800.88/- (Rupees One Crore Forty One Lakhs Ninety Thousand Eight hundred and eighty eight paise) only with 12% interest per annum thereon from the period of supply till payment.

In view of above facts and circumstances, as explained above, I request you to withdraw the office order being Memo No. UPMSCL/MD/QC/2025/724 dated 26.08.2025 along with show cause letter being Ref No. UPMSCL/MD/QC/2025/490 dated 16.07.2025 and disburse the pending due amount of Rs. 1,41,90,800.88/- (Rupees One Crore Forty One Lakhs Ninety Thousand Eight hundred and eighty eight paise) only towards supplied drugs of Benzyl Benzoate 25% W/W 100 ml bottle with 12% interest thereon per annum to be calculated till the payment from the date of supply in terms of the letter and spirit of order passed by the Hon'ble High Court, Calcutta in W.P.A. No. 21809 of 2025 failing which appropriate legal action will follow and you will be liable for all costs and consequences.

This fact has not been disputed or denied by the Company that during confirmatory testing of the drug by the empanelled labs of UPMSCL the Batches supplied by the Company did not meet the requirement of acceptance criteria of microbiological testing of non-sterile products for Pharmaceutical use as provided in Indian Pharmacopeia. Rather an objection has been raised that the drug in question is not subject to microbial testing and no TAC TFC count are prescribed for the Drug in question.

The company has stated that the test report provided by the UPMSCL empanelled labs did not match the test report provided by the Company. It further says that in petitioner's own test report and approved laboratories (NABL Accredited) provided by the Company all the alleged 26 batches were found to be of standard quality. The aforesaid result is inevitable because it is admitted position that the test report provided by the company does not cover Microbiological testing of the drug in question. The Drug supplied by the Company has been declared as Not of Standard Quality as it failed in microbiological testing of the drug by two or more than two laboratories.

It has been mentioned in the written representation by the company that the test report provided by the Company does not cover the microbiological tests for TAC and TFC because Indian Pharmacopoeia, 2022 and its addendum-2024 does not prescribe Microbiological Test for Non Sterile products used for cutaneous purpose. Further on the basis of the test report submitted by the Company the UPMSCL has accepted the batches.

Section 16 of the Drug and Cosmetics Rules, 1945 and Rule 124 of the Drugs and Cosmetics Rules, 1945 provides the Standard of Drug. As per Section 16 of the Drug and Cosmetics Rules, 1945 read with Rule 124 of the Drugs and Cosmetics Rules, 1945 If the drug is included in Indian Pharmacopoeia the Standard for identity, purity and strength shall be those as may be specified in the edition of the Indian Pharmacopoeia for the time being in force. The Drug in question is included in Indian Pharmacopoeia and therefore it has to meet the Standard for identity, purity and strength shall be those as may be specified in the edition of the Indian Pharmacopoeia for the time being in force . Indian Pharmacopoeia 2022, General Chapter, page 1300 provides that "During Manufacture, packing, storage and distribution of creams, suitable means shall be taken to ensure their microbial Quality. Further acceptance criteria for microbiological quality for non-sterile for pharmaceutical use is clearly provided in Chapter 2.2.9. Table 5 of the said Chapter provides the Acceptance Criterial for Microbiological Quality of nonsterile substances for pharmaceutical use.

The Company through its Advocate Sri Ushananda Jana vide his letter dated 20.11.2025 has provided the copy of the RTI reply dated 17.11.2025 by State Public Information Officer 7 Director, SDCRL pursuant to the Application dated 04.11.2025 submitted by Sri Ushananda. The query raised and the reply given by the concerned information officer is as follows:

Question Asked	Reply Given
Whether microbiological test is applicable in Benzyl Benzoate application I.P. 255 W/W since monograph of Indian Pharmacopeia-2022 did not prescribe microbiological test. Apart from above, the general chapter of India Pharmacopeia addendum-2024 did not prescribe any specifications for Total Aerobic Count (TAC), Total Fungal Count (TFC) & specific organisms for non-sterile dosage forms having route of administration of cutaneous use. It is pertinent to note that Benzyl Benzoate application I.P. is for cutaneous use. Photocopy of respective pages are annexed herewith for your ready reference.	The test parameters of Benzyl Benzoate application IP 25% W/W as per Indian Pharmacopeia 2022. Monograph and General Chapter of IP' 2022 namely "Microbial contamination of non-sterile products" does not include any Microbiological tests.

Though the said letter was submitted after the oral hearing being completed. However in the interest of justice the said letter is also considered. From the bare perusal of the aforesaid reply given by the State Public Information Officer it appears that it is only his own opinion and is also contrary to the Indian Pharmacopeia' 2022. Chapter 2.2.9 Microbial Contamination in Non-sterile Products reads as under:

Acceptance criteria for Microbiological, quality of non-sterile pharmaceutical substances and nor sterile doses forms

This provides acceptance criteria for microbiological quality of non-sterile substance of force, tickle, use, and non-sterile doses forms, unless otherwise specified in the monogram.

If microorganism are present in a pharmaceutical preparation, they can reduce or in activate the therapeutic activity of the product or can adversely affect the health of the patient. Hence, pharmaceutical preparations should have low bioburden and they should not have specified microorganism, which are harmful.

Microbial examination of non-sterile product is performed according to the methods given above. Acceptance criteria for microbiological, quality of non-sterile substances for formal Topical use and non-sterile pharmaceutical product based upon the total Aerobic count and the total fungal count are given in table 5, and 6, respectively.

Thus the reply given by the State Public Information Officer says that the test parameters of Benzyl Benzoate application IP 25% W/W as per Indian Pharmacopeia 2022. However it further says that "Microbial contamination of non-sterile products" does not include any Microbiological tests, which is directly contrary to the Indian Pharmacopeia' 2022 as quoted above and as such cannot be accepted.

Further in paragraph 18 of the written representation it is mention that non-sterile substances are genus whereas cutaneous preparations are species. Thus on this count also if a specific quality standard are provided for the genus then the species falling under the said genus must confirm the quality standards provided for the genus unless any different or specific standard is provided for the species.

Thus the submission of the Company that the drug in question was not required to meet the criteria of microbiological testing as provided in the Indian Pharmacopoeia 2022 is untenable.

The averment made by the Company that the test reports are fraudulent is nothing but an after thought because in their earlier reply dated 21.07.2025 they did not allege any said allegation. Further the said allegation is also unfounded because the Microbiological tests have been conducted by three different and independent laboratories. After considering the test report of all the three laboratories, when any batch was declared as Not of Standard Quality by two or more Laboratories then only the said drug was declared as Not of Standard Quality. Thus it cannot be said that there was any tempering in the test reports.

It has been stated that the Test Reports of the empanelled Laboratories did not highlight the TAC and TFC. The said averment is contrary to the records. In every test reports the aforesaid facts have been specified. However in some report since the Counts were either too high or too low so as to report exact count and therefore observation has been made to the aforesaid effect. The submission that all of sudden in March 2025 UPMSCL has started the microbiological testing is also unfounded and misleading. All the drug batches which are subject matter of dispute were manufactured in the month of January and February 2025 and thus their testing in March 2025 is quite natural and raises no doubt on the correctness of testing. The tender condition no. 11 authorises the UPMSCL to conduct final confirmatory quality testing to ensure the quality of the

product. Thus the testing done by the UPMSCL is completely lawful and justified because in order to ensure public health all safety is to be ensured by the UPMSCL.

It has been further stated by the Company that the Laboratories which have tested the drug in question did not sent the Test report to the licensing authority or approving authority as per Clause (g) of Rule 150 E of the Drug and Cosmetics Rules, 1945. It is stated that Licensing Authority of the approved laboratories has power to suspend or cancel the license of an approved laboratory on failure to comply with the provisions of the Drug and Cosmetics Act and Rules.

I find that the aforesaid submission of the company is not relevant for deciding whether the company should be Blacklisted for supplying 26 batches of drug which were found "not of standard quality" in two and more than two laboratories test during confirmatory quality testing. The action by the Licensing authority against the lab conducting test has no relation with the blacklisting of the Company.

In paragraph 9 of the written representation submitted and pressed during oral hearing it has been stated that the Kemecos India Private Limited submitted detailed written response on 21.07.2025 clarifying that standard quality of Benzyl Benzoate Application 25%w/w 100 ml bottle were supplied since active ingredient of the said formulation is within limit as revealed from Analytical Test Reports. Moreover there is no objection/complaint since 2022 regarding public safety. The supplied drug is under the purview of Drugs and Cosmetic Act, 1940 and Rules thereunder. The said drug was not tested by Govt. analyst of Central Drugs Laboratory, Kolkata. The incorporation of microbiological test is the novation of the Tender clauses. Therefore the dispute regarding not of standard quality does not arise at all. The dispute regarding quality of the alleged drug is not arbitrable since Drugs and Cosmetics Act, is not a civil Act. UPMSCL has failed to discharge its obligation as per tender clause 14 regarding payment terms i.e. within 45 days of completion of supply based on quality clearance status.

With regard to the aforesaid submission of the Company it may be pertinent to note that as per clause 11 of the tender, UPMSCL has authority to conduct the confirmatory testing on any drug supplied by the company. Further it is also mandatory for the any drug to clear the acceptance criteria as provided in Indian Pharmacopeia, 2022. Thus exercising its powers as per clause 11 of the tender condition and as per provision contained in Drug and Cosmetics Act and Rules the testing was conducted in which 26 batches supplied by the company as described above were found "not of standard quality". No objection or complaint regarding public safety was received in past will not render the drug which was found "not of standard quality" as acceptable for all time to come. Acceptance of any drug which failed in testing will amount to deliberately putting the public safety at risk.

It has been argued by the Company that the black-listing of the company vide order dated 26.08.2025 is violative of Section 25 (3) and 25 (4) and Section 23 of the Drug and Cosmetics Act, 1945. Further the report is not signed by the Government Analysts. A perusal of Section 25 of the Drug and Cosmetics Act, 1945 will reveal that the provisions of Section 25 of the Act will be applicable only when the drug has been tested by the Government Analysts. Since in the instant case the drug in question was not tested by the Government Analysts and therefore provisions of

Section 25 of the Act are not applicable and therefore the submission of the Company is liable to be rejected.

It may be pertinent to note that Drug and Cosmetics Rules, 1945 was amended and various provision were amended/added/substituted by G.S.R. 223(E), dated 18th March, 2019. Thereafter Rule 150 B, 150C, 150 E of the Drug and Cosmetics Rules, 1945 were substituted with the new provision and now the laboratories may be approved, licensed and conduct testing for procurement agencies also. A new Form 39 A was inserted. As per Rule 150 E(f) of the Drug and Cosmetics Rules, 1945 the report can be given in Form 39-A.

Thus the test conducted by the empanelled laboratories (NABL accredited) of the UPMSCL at the request of the UPMSCL in order to conduct the confirmatory quality testing as per Clause 11 of the tender condition was in complete conformity with the Drug and Cosmetics Act and Rules and there is no merit in the submission that the order dated 26.08.2025 or the testing done the laboratories was contrary to any of the provisions of the Drug and Cosmetics Act as such the aforesaid submission is rejected.

The argument of the representative of the Company that the action taken by the Corporation is violative of Article 19(1) (g) of the Constitution of India has not merits because the freedom guaranteed under 19(1) (g) of the Constitution of India is not absolute and the same is subject to restriction. In the instant case the drug supplied by the Company was found "Not of Standard Quality" and under no circumstance the drug which is "Not of Standard Quality" can be accepted. Thus the action was taken against the company in the interest of general public.

The submissions of the representative of the Company that the black-listing of the company is violative of Article 14 of the Constitution of India also has no legs to stand because the company has been blacklisted as per the terms and conditions of the contract and in accordance with law when 26 batches of the drug supplied by the Company were found to be "Not of Standard Quality" and therefore action of the corporation can neither be said to be arbitrary or violative of Article 14 of the Constitution of India.

Thus in view of aforesaid discussion after considering the oral submissions of the representatives of the Company, their written submission and records in the matter, I do not find any reason to cancel the order dated 26.08.2025. Thus the order dated 26.08.2025, which
was kept is abeyance in compliance of the order dated 26.09.2025 passed by the Hon'ble Calcutta High Court is hereby confirmed and following actions will be implemented :

(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 (vi), Company 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 further opportunity of 15 days is being given to the company to recall the drug batches declared as "Not of Standard Quality", thereafter 0.2% demurrage shall be levied on the value of corresponding quantity lying at District Drug warehouses.

(C) As per tender condition 11 (vii) In case the company does not take back the stock of Twenty six "Not of Standard Quality" 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.

(D) 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) since 26 Drug batches of "Benzyl Benzoate Application: 25% w/w (-) 100 ml Bottle" to different District Drug warehouses of Uttar Pradesh Medical Supplies Corporation Ltd have been found as "Not of Standard Quality" as such, Kemecos India Private Limited is, hereby, blacklisted for the drug "Benzyl Benzoate Application: 25% w/w (-) 100 ml Bottle" for three years with effect from 26.08.2025.

Managing Director
UPMSCL

Endorsement No.: UPMSCL/05/2025-26/1512 **Dated :** 29-Jan-2026

Copy to the following for information & necessary action:

1. Finance Controller, UPMSCL to ensure that payment is not processed for "Not of Standard Quality" declared Drug batch.
2. Drug Licensing & Controlling Authority, UP, Office of Commissioner, Food Safety & Drug Administration, Sector-C, Aliganj, Lucknow.
3. Senior Consultant, Quality Control /SCM, UPMSCL.
4. Consultant, Drug Procurement, UPMSCL.
5. General Manager, Quality Control, UPMSCL.
6. General Manager, Drug Procurement, 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. Warehouse Pharmacist, All District Drug Warehouses of UPMSCL.

Managing Director
UPMSCL