

MICROBIOLOGY SPECIFICATION SHEET

Compendial microbiological screening capabilities aligned with USP <61>, <62>, and <71>. Methods are routinely validated for the matrices listed below.

1. BIOLOGICAL SCREENINGS & USP CRITERIA

SCREENING PROFILE	METHODOLOGY / INCUBATION PARAMETERS	SPECIFICATION LIMIT	TAT
Total Aerobic Count (TAMC)	USP <61> bio-burden plating. Soybean-Casein Digest Agar at 32.5°C ± 2.5°C for 48-72 hours.	< 10 CFU/g or CFU/mL	5 Days
Total Combined Mold / Yeast (TYMC)	USP <61> bio-burden plating. Sabouraud Dextrose Agar at 22.5°C ± 2.5°C for 5-7 days.	< 10 CFU/g or CFU/mL	7 Days
Specified Organisms	USP <62> selective enrichment for E. coli, S. aureus, P. aeruginosa, Salmonella spp.	Absent / gram or mL	7 Days
Sterility	USP <71> direct inoculation or membrane filtration into FTM & TSB. 14-day incubation.	No Growth	14 Days
Antimicrobial Effectiveness	USP <51> preservative challenge across 28-day exposure timeline.	Per Category 1-4 Criteria	30 Days

2. SAMPLE HANDLING

- Ship under cold chain (2-8°C) within 24 hours of collection.
- Provide minimum 10 g or 10 mL per assay, plus 50% retention.
- Note any inherent antimicrobial activity so neutralization can be validated.