Lactose Monohydrate, Sterile (Gamma Irradiated)

Intended Use
Lactose Monohydrate, Sterile (Gamma irradiated) is used for media fill trails.

Summary
Routine sampling for sterility testing is not sensitive enough to detect any low-level contamination in sterile pharmaceutical formulations. Sample numbers are too small and only gross contamination is likely to be detected. Pharmaceutical manufactures therefore need other means of guaranteeing the quality of their product. This is why process stimulations (Media Fill Run) supported by environmental monitoring is must in pharmaceutical industry. The FDA guidelines have recommended using SCDM for liquid injectable and lactose for dry injectable. Regular dehydrated culture media or lactose is usually supplied in non-sterile form which carries high bioburden and should not be directly taken into a controlled area therefore irradiated sterile SCDM/Lactose is used for media fill run.

Principle
During media fill run for validation of dry injectable Gamma irradiated lactose is dispersed into individual vial/ampules. After completion of filling process individual vial is reconstituted with sterile distilled water (As per label claim of injection). Reconstituted vials an incubated at 35°C-37°C and monitored till 14 days.

Storage and Stability
Store dehydrated medium below 30°C in tightly closed container and the prepared medium at 2°C-8°C. Avoid freezing and overheating. Use before expiry date on the label. Once opened keep powdered medium closed to avoid hydration.

Quality Control
I) Before Gamma Irradiation

Dehydrated Appearance: White or almost white amorphous powder, may or may not have lumps.

Solubility: Freely but slowly soluble in water, practically insoluble in ethanol (95%) and (96%).

Colour and Clarity of the Prepared Medium: The solution is clear and not more intensely coloured than reference solution by 7.

pH	: 3-6
Absorbance - At 400NM	: <= 0.040
Absorbance - At 210-220NM IP/USP/BP/EP	: <= 0.250
Absorbance - At 270-300NM IP/USP/BP/EP	: <= 0.070
Acidity and Alkalinity	: <= 0.40
Residue on Ignition / Sulphated ash	: <= 0.10
Heavy Metals	: <= 5.0 ppm
Identification A- By IR	: To comply
Identification B- By TLC	: To comply
Identification D- Water	: To comply
Loss on Drying	: <= 0.50
Arsenic	: <= 1 ppm
Microbial Contamination	
Total aerobic microbial count	: <=100/g
Escherichia coli	: Absent/l0g
Salmonella	: Absent/l0g
Shigella	: Absent/l0g
Particle Size Distribution	
Thru 250µ IH test by alpine air jet	:100%
Thru 150µ IH test by alpine air jet	:100%
Thru 100µ IH test by alpine air jet	:100%
Thru 45µ IH test by alpine air jet	:65%
Specific Optical Rotation	: Between +54.4° to +55.9°
Bulk density (Untapped)	: About 0.600 g/mL
Bulk density (Tapped)	: About 0.900 g/mL

II) After Gamma Irradiation
Sterility Test - FTM and SCDM tubes shall remain sterile (without any growth) till 14 days.

Note:
SCDM - Soyabean Casein Digest Medium
FTM - Fluid Thioglycollate Medium
Gamma irradiation dose - 25 kilo Gray.

III) Cultural Response
Cultural response observed after an incubation at 35-37°C for 18-24 hours by preparing Phenol Red Lactose Broth, using 0.5% of Lactose Monohydrate, sterile as an ingredient.

Organism (ATCC)	Growth	Acid	Gas
Citrobacter freundii (8090)	Good	Positive reaction, yellow colour	Positive reaction
Escherichia coli (25922)	Good	Positive reaction, yellow colour	Positive reaction
Klebsiella aerogenes (13048)	Good	Positive reaction, yellow colour	Positive reaction
Klebsiella pneumoniae (13883)	Good	Positive reaction, yellow colour	Positive reaction
Proteus hauseri (13315)	Good	Negative reaction, no colour change	Negative reaction
Salmonella enterica subsp. *enterica* serovar *Typhimurium* (14028)	Good	Negative reaction, no colour change	Negative reaction
Shigella flexneri serotype 2b (12022)	Good	Negative reaction, no colour change	Negative reaction

Performance and Evaluation
Performance of the product is dependent on following parameters as per product label claim:
1. Directions
2. Storage
3. Expiry

Warranty
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. US Food and Drug Adm; 1998, Bacteriological Analytical Manual, 8th Analytical Ed; Rev. A, AOAC, International, Gaitherburg, Md.
2. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:
Cat No.	Product description	Pack Size
201120110500	Dehydrated Culture Media	500 g