D-Mannitol, A. R. Sterile (Gamma - Irradiated)

Intended Use
D-Mannitol, A. R. 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 manufacturers 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 D-Mannitol for dry injectable. Regular dehydrated culture media or D-Mannitol 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/D-Mannitol is used for Media Fill Run. Irradiation also assumes that sterile products are free from *Mycoplasma.*

Principle
During Media Fill Run for validation of dry injectable Gamma Irradiated D-Mannitol 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 Irradiated
Appearance: White crystalline powder
Solubility: Clear & colourless
Identification A : Specific Optical Rotation : + 23 - + 25°
Identification B : Melting Point : 165-170°C
Identification C : Infrared absorption spectrophotometry : Conformity
Loss on drying : NMT 0.30% w/w
Microbial Contamination
TAMC : NMT 10^3 CFU/g
TYMC : NMT 10^2 CFU/g
Escherichia coli : Absent
Salmonella : Absent (As per BP/Ph.Eur)
Reducing sugars : NMT 0.1%
Related substances:
Unspecified impurities : NMT 0.1%
Total impurities : NMT 2.0% (As per BP/Ph.Eur)
Nickel : NMT 1µg/g
Lead : NMT 0.5ppm (As per BP/Ph.Eur)
Bacterial endotoxins : NMT 2.5 IU/g
Assay : 98.0% - 102.0%

II) After Gamma Irradiated
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
The material was subjected to Gamma irradiation for dose of 25 kilo Gray.

Performance and Evaluation

Performance of the product is dependent on following parameters as per product label claim:

1. Directions
2. Storage
3. Expiry

Warranty

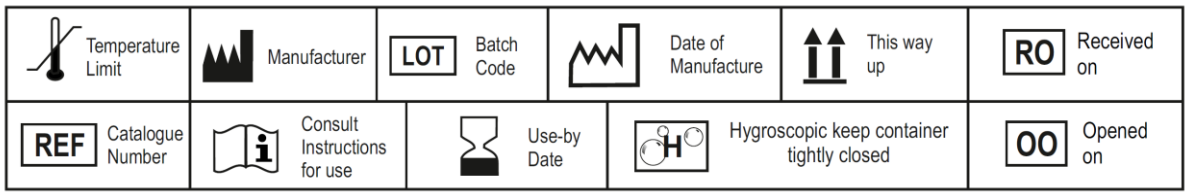
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

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
201040340500	Dehydrated Culture Media	500 g
201040345000	Dehydrated Culture Media	5 k
201040349925	Dehydrated Culture Media	25 k



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Disclaimer

Information provided is based on our inhouse technical data on file, it is recommended that user should validate at his end for suitable use of the product.