

Lactose Monohydrate, Sterile (Gamma Irradiated)

Intended Use

Lactose Monohydrate, Sterile (Gamma irradiated) is used for media fill trials.

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 are 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 |
| <i>Escherichia coli</i> | : Absent/10g |
| <i>Salmonella</i> | : Absent/10g |
| <i>Shigella</i> | : Absent/10g |

Particle Size Distribution

| | |
|--|----------------------------|
| Thru 250 μ IH test by alpine air jet | :100% |
| Thru 150 μ IH test by alpine air jet | :100% |
| Thru 100 μ IH test by alpine air jet | :100% |
| Thru 45 μ 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 |
|--|--------|-------------------------------------|-------------------|
| <i>Citrobacter freundii</i> (8090) | Good | Positive reaction, yellow colour | Positive reaction |
| <i>Escherichia coli</i> (25922) | Good | Positive reaction, yellow colour | Positive reaction |
| <i>Klebsiella aerogenes</i> (13048) | Good | Positive reaction, yellow colour | Positive reaction |
| <i>Klebsiella pneumoniae</i> (13883) | Good | Positive reaction, yellow colour | Positive reaction |
| <i>Proteus hauseri</i> (13315) | Good | Negative reaction, no colour change | Negative reaction |
| <i>Salmonella enterica</i> subsp. <i>enterica</i> serovar <i>Typhimurium</i> (14028) | Good | Negative reaction, no colour change | Negative reaction |
| <i>Shigella flexneri</i> 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. 201120110500 | Product description Dehydrated Culture Media | Pack Size 500 g |
|--------------------------------|--|---------------------------|

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|---|--|---|---|---|---|---|
|  Temperature Limit |  Manufacturer |  LOT | Batch Code |  Date of Manufacture |  This way up |  RO Received on |
| REF Catalogue Number |  Consult Instructions for use |  Use-by Date |  HC | Hygroscopic keep container tightly closed | OO Opened on | |

Revision: 0825/VER-03

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.