Soyabean Casein Digest Medium, Sterile Powder

Intended Use
Soyabean Casein Digest Medium, Sterile Powder is used for evaluation of sterility in manufacturing process.

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 new FDA guidelines pay particular attention to this aspect of aseptic processing and it is becoming an area requiring more work and focus to satisfy the regulators. The FDA guidelines have recommended using Soyabean Casein Digest Medium - a highly nutritious general-purpose medium that is ideal for microbiological media fill. It also recommended that in order to more closely mimic the process, the culture medium should be filtered into the process, just as would occur to liquid pharmaceutical product. Regular dehydrated culture media is usually supplied in non-sterile form, which carries a high bioburden and should not take directly into a controlled area. Therefore, Gamma irradiated, sterile SCDM powder is used for media fills. Irradiation of media also assures the sterile medium is free from *Mycoplasma*.

Principle
The combination of pancreatic digest of casein and papaic digest of soyabean meal makes the medium highly nutritious by supplying organic nitrogen, particularly amino acids and long chain peptides. Dextrose is the fermentable source of carbon and dibasic potassium phosphate serves as the buffer in the medium. Sodium chloride maintains osmotic balance. This medium, which has sterilized by gamma irradiation, can be directly used for media-fill runs as recommended by FDA guidelines.

Formula*

Ingredients	**g/L**
Pancreatic Digest of Casein	17.0
Papaic Digest of Soyabean Meal	3.0
Sodium Chloride	5.0
Dextrose Monohydrate	2.5
Dibasic Potassium Phosphate	2.5
Final pH (at 25°C)	7.3 ± 0.2

*Adjusted to suit performance parameters.

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

Directions
1. Sterile powder can be used directly for the evaluation of sterility in manufacturing process.
2. For sterile liquid medium aseptically add 29.77 g (the equivalent weight of dehydrated medium per litre) of the powder in 1000 mL sterile distilled water.
3. Heat if necessary, to dissolve the powder completely.
4. DO NOT AUTOCLAVE OR OVERHEAT.
5. Excessive heating is detrimental.
6. Dispense aseptically in sterile tubes or flasks as desired.

Quality Control

Dehydrated Appearance: Cream to yellow coloured, homogeneous, free flowing powder.
Prepared Appearance: Light yellow to amber coloured, clear solution without any precipitate.
Sterility Test (Membrane Filtration Method): No bacterial and fungal growth is observed after 14 days at 30°C-35°C in FTM and 20°C-25°C in SCDM.
Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP/IP and growth is observed after an incubation at 30°C-35°C for ≤ 3 days for bacteria and ≤ 5 days for fungi.
Growth Promoting Properties: The test results observed are within the specified temperature and shortest period of time, inoculating ≤100 cfu (at 30°C-35°C for ≤ 3 days for bacteria and ≤ 5 days for fungi).

Growth Promoting

Organism (ATCC)	**Growth**	**Incubation Temperature**
Staphylococcus aureus subsp. *aureus* (6538)	Good	30°C-35°C
Pseudomonas aeruginosa (9027)	Good	30°C-35°C
Bacillus spizizenii (6633)	Good	30°C-35°C
Candida albicans 3147 (10231)	Good	30°C-35°C
Aspergillus brasiliensis WLR I034(120) (16404)	Good	30°C-35°C

Validation and Growth Promotion: Growth promotion is carried out at an incubation of 20°C - 25°C for ≤ 3 days for bacteria and ≤ 5 days for fungi as per USP/EP/JP/IP.

Organism (ATCC)	**Growth**	**Incubation Temperature**
Candida albicans 3147 (10231)	Good	20°C - 25°C
Bacillus spizizenii (6633)	Good	20°C - 25°C
Aspergillus brasiliensis WLRI 034(120) (16404)	Good	20°C - 25°C

Note: Inoculum cfu for good growth is 10 - 100.

Performance and Evaluation

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

Warranty

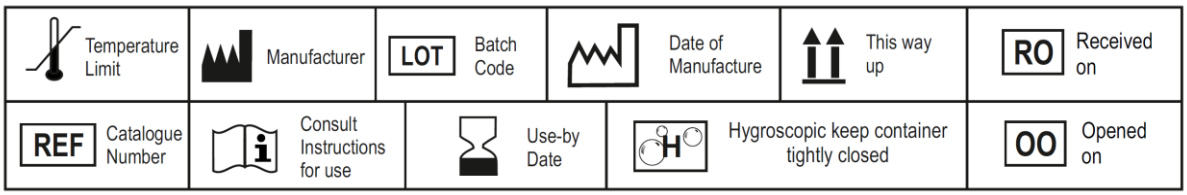
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

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
201190270500	Dehydrated Culture Media	500 g
201190272500	Dehydrated Culture Media	2.5 k
201190275000	Dehydrated Culture Media	5 k
201190279925	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.