Soyabean Medium, Sterile Powder VEG

Intended Use
Soyabean Medium, Sterile Powder VEG is a medium used for evaluation of sterility in manufacturing process.

Summary
Soyabean Medium, Sterile powder VEG is prepared by completely replacing animal based Pancreatic digest of casein of Soyabean Casein Digest Medium, Sterile powder with vegetable based Veg hydrolysate. This makes the medium free of BSE / TSE associated risks. This medium can be used for the same purpose of Soyabean Casein Digest Medium, which is recommended by various pharmacopoeias as sterility testing medium. It is also used for the sensitivity testing by the tube dilution method for antimicrobial agents.

Principle
The combination of Veg Hydrolysate and Papaic Digest of Soyabean Meal makes this medium highly nutritious by supplying organic nitrogen, particularly amino acids and long chain peptides. Sodium Chloride maintains osmotic balance. Dextrose serves as the carbon source and dipotassium phosphate buffers the medium. This medium, which has sterilized by gamma irradiation, can be directly used for media-fill runs.

Formula*

Ingredients	g/L
Veg Hydrolysate	17.0
Papaic Digest of Soyabean Meal	3.0
Sodium Chloride	5.0
Dextrose	2.5
Dipotassium 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 30.00 g of the powder in 1000 mL sterile purified / distilled water.
3. Mix well to dissolve the powder completely.
4. 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	Incubation Period
Staphylococcus aureus subsp. *aureus* (6538)	Good	30°C-35°C	18 Hours
Pseudomonas aeruginosa (9027)	Good	30°C-35°C	18 Hours
Bacillus spizizenii (6633)	Good	30°C-35°C	18 Hours
Candida albicans 3147 (10231)	Good	30°C-35°C	24 Hours
Aspergillus brasiliensis WLRI 034(120) (16404)	Good	30°C-35°C	48 Hours

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	Incubation Period
Candida albicans 3147 (10231)	Good	20°C - 25°C	48 Hours
Bacillus spizizenii (6633)	Good	20°C - 25°C	48 Hours
Aspergillus brasiliensis WLRI 034(120) (16404)	Good	20°C - 25°C	72 Hours

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

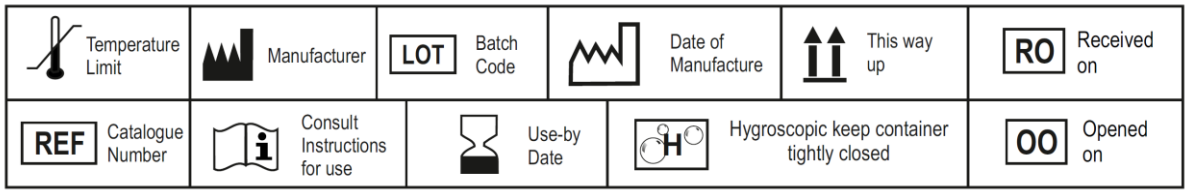
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. The United States Pharmacopoeia / National Formulary, 2012, 35.The United States Pharmacopeial Convention Inc.Rockville, MD.
2. Indian Pharmacopeia, 2014, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.
3. Wright and Welch, 1959-60, Antibiotics Ann., 61.
4. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201191660500	Dehydrated Culture Media	500 g



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.