Technical Data

Soyabean HiVeg® Medium, Sterile Powder (Tryptone Soya HiVeg® Broth, Sterile Powder) MV011G

Intended Use:

It is a γ-irradiated sterile powder recommended for the evaluation of sterility in manufacturing process.

Composition**

Ingredients	g / L
HiVeg® hydrolysate	17.000
Soya peptone	3.000
Sodium chloride	5.000
Dipotassium hydrogen phosphate	2.500
Dextrose (Glucose)	2.500
Final pH (at 25°C)	7.3±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Sterile powder can be used directly for the evaluation of sterility in manufacturing process. For sterile liquid medium aseptically add 30.0 grams in 1000 ml sterile purified/ distilled water. Heat if necessary to dissolve the medium completely. DO NOT AUTOCLAVE OR OVERHEAT. Excessive heating is detrimental. Dispense aseptically in sterile tubes or flasks as desired. (Sterilized by gamma irradiation) Note: If any fibres are observed in the solution it is recommended to filter the solution through 0.22 micron filter to eliminate any possibility of presence of fibres.

Principle And Interpretation

Soyabean Casein Digest Medium is recommended by various pharmacopoeia as sterility testing medium (1, 2). It is also used for the sensitivity testing by the tube dilution method for antimicrobial agents (3). Soyabean HiVeg® Medium, Sterile Powder is prepared by using vegetable peptones in place of animal based peptones which make the media free of BSE/TSE risks. The combination of HiVeg® hydrolysate and soya peptone makes this medium nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Dextrose and dipotassium phosphate serves as the carbohydrate source and the buffer in the medium. Sodium chloride maintains the osmotic balance of the medium.

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (4). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Biochemical characterization is necessary to be performed on colonies from pure cultures for further identification.
2. This medium is general purpose medium and may not support the growth of fastidious organisms.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow may have green tinge homogeneous free flowing powder

Colour and Clarity of prepared medium

Light amber coloured clear solution

Reaction

Reaction of 3.0% w/v aqueous solution at 25°C. pH : 7.3±0.2

pH

7.10-7.50

Sterility Testing

No growth is observed after 14 days for Bacteria at 30-35°C and for Fungi at 20-25°C.

Test for Mycoplasma (PCR)

Negative for Mycoplasma

Stability test

Light yellow coloured clear solution without any precipitation or sedimentation at room temperature for 7 days

Growth promoting properties

Clearly visible growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating <=100cfu (at 30-35°C for 18-24 hours).

Sterility Testing + Validation

The medium is tested with suitable strains of microrganisms inoculating <=100cfu and incubating at 20-25°C for not more than 3 days in case of bacteria and not more than 5 days in case of fungi.

Organism	Inoculum (CFU)	Growth	Incubation temperature	Incubation period
Growth promoting				
Staphylococcus aureus subsp. *aureus* ATCC 6538 (00032*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
Escherichia coli ATCC 8739 (00012*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
Escherichia coli ATCC 25922 (00013*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
^*Pseudomonas paraeruginosa* ATCC 9027 (00026*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
** *Bacillus spizizenii* ATCC 6633 (00003*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
$ *Kokuria rhizophila* ATCC 9341	50 -100	luxuriant	30 -35 °C	18 -24 hrs
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
Salmonella Abony NCTC 6017 (00029*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
Sterility Testing- Growth promotion+Validation				
Staphylococcus aureus subsp. *aureus* ATCC 6538 (00032*)	50 -100	luxuriant	20 -25 °C	<=3 d
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	50 -100	luxuriant	20 -25 °C	<=3 d
Escherichia coli ATCC 8739 (00012*)	50 -100	luxuriant	20 -25 °C	<=3 d
Escherichia coli ATCC 25922 (00013*)	50 -100	luxuriant	20 -25 °C	<=3 d
^*Pseudomonas paraeruginosa* ATCC 9027 (00026*)	50 -100	luxuriant	20 -25 °C	<=3 d
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	luxuriant	20 -25 °C	<=3 d
** *Bacillus spizizenii* ATCC 6633 (00003*)	50 -100	luxuriant	20 -25 °C	<=3 d

$ *Kokuria rhizophila* ATCC 9341	50 -100	luxuriant	20 -25 °C	<=3 d
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	20 -25 °C	<=3 d
Salmonella Abony NCTC 6017 (00029*)	50 -100	luxuriant	20 -25 °C	<=3 d
Candida albicans ATCC 10231 (00054*)	50 -100	luxuriant	20 -25 °C	<=5 d
Candida albicans ATCC 2091 (00055*)	50 -100	luxuriant	20 -25 °C	<=5 d
#*Aspergillus brasiliensis* ATCC 16404 (00053*)	50 -100	luxuriant	20 -25 °C	<=5 d

Key :(*) Corresponding WDCM numbers

^ Formerly known as *Pseudomonas aeruginosa* **Formerly known as *Bacillus subtilis* subsp. *spizizenii*

Formerly known as *Aspergillus niger* $ Formerly known as *Micrococcus luteus*

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 15-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (2,5).

Reference

1. Indian Pharmacopeia, 2010, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
3. Wright and Welch, 1959-60, Antibiotics Ann., 61.
4. The United States Pharmacopoeia / National Formulary, 2012, 35.The United States Pharmacopeial Convention Inc., Rockville, MD.
5. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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