

Quality Control

Appearance

Sterile Soyabean Casein Digest medium in a glass vial.

Colour

Light yellow coloured clear solution

Quantity of Medium

100 ml of medium in glass vial.

pH

7.10- 7.50

Growth Promotion Test

In accordance with the harmonized method of USP/EP/BP/JP.

Sterility Check

Passes release criteria.

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 ≤ 100 cfu (at 30-35°C for 18-24 hours for bacteria). Growth promotion is carried out as per USP/EP/BP/JP.

Sterility Testing + Validation

The medium is tested with suitable strains of microorganisms inoculating ≤ 100 cfu 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 ^s	Incubation period	Incubation temperature
Growth promoting				
<i>Salmonella</i> Abony NCTC 6017 (00029*)	≤ 100	luxuriant	18 -24 hrs	30 -35 °C
<i>Salmonella</i> Typhimurium ATCC 14028 (00031*)	≤ 100	luxuriant	18 -24 hrs	30 -35 °C
^ <i>Pseudomonas paraeruginosa</i> ATCC 9027 (00026*)	≤ 100	luxuriant	18 -24 hrs	30 -35 °C
<i>Escherichia coli</i> ATCC 8739 (00012*)	≤ 100	luxuriant	18 -24 hrs	30 -35 °C
\$\$ <i>Bacillus spizizeni</i> ATCC 6633 (00003*)	≤ 100	luxuriant	18 -24 hrs	30 -35 °C
## <i>Kokuria rhizophila</i> ATCC 9341	≤ 100	luxuriant	18 -24 hrs	30 -35 °C
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 6538 (00032*)	≤ 100	luxuriant	18 -24 hrs	30 -35 °C
Sterility Testing- Growth promotion+Validation				
^ <i>Pseudomonas paraeruginosa</i> ATCC 9027 (00026*)	≤ 100	luxuriant	≤ 3 d	20 -25 °C
\$\$ <i>Bacillus spizizenii</i> ATCC 6633 (00003*)	≤ 100	luxuriant	≤ 3 d	20 -25 °C
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 6538 (00032*)	≤ 100	luxuriant	≤ 3 d	20 -25 °C
## <i>Kokuria rhizophila</i> ATCC 9341	≤ 100	luxuriant	≤ 3 d	20 -25 °C
<i>Candida albicans</i> ATCC 10231 (00054*)	≤ 100	luxuriant	≤ 5 d	20 -25 °C
# <i>Aspergillus brasiliensis</i> ATCC 16404 (00053*)	≤ 100	luxuriant	≤ 5 d	20 -25 °C

Key : (*) Corresponding WDCM numbers,

- Formerly known as *Aspergillus niger*,

^ Formerly known as *Pseudomonas aeruginosa*

\$ - Luxuriant growth refers to turbid growth

- Formerly known as *Micrococcus luteus*

\$\$- Formerly known as *Bacillus subtilis* subsp. *spizizenii*

Storage and Shelf Life

Store between 15-30°C. Use before expiry date on the label. 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 (7,8).

Reference

- 1.The British Pharmacopoeia, 2022, Medicines and Healthcare products Regulatory Agency.
- 2.European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.
- 3.The Japanese Pharmacopoeia, 17th edition, 2016, The Ministry of Health, Labour and welfare.
- 4.Indian Pharmacopoeia, Addendum 2024, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.
- 5.The United States Pharmacopoeia-National Formulatory (USP-NF), 2022.
- 6.Wright and Welch, 1959-60, Antibiotics Ann., 61.
- 7.Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
- 8.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.

Revision :03/2024

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