



## Quality Control

### Appearance

Gelatin capsule containing cream to yellow coloured granulated media

### Colour and Clarity of prepared medium

Light yellow coloured clear solution without any precipitate.

### Quantity

Each capsule contains 7.5 grams of medium sufficient for 250 ml media

### Reaction

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

### pH

7.10-7.50

### Cultural Response

Cultural characteristics observed after an incubation at 30-35°C for ≤ 3 days for Bacteria and at 20-25°C for ≤5 days for fungi

Organism	Growth	Incubation period	Inoculum (CFU)	Incubation temperature
<b>Growth promoting</b>				
<i>Escherichia coli</i> ATCC 8739	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Escherichia coli</i> ATCC 25922	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Staphylococcus aureus</i> ATCC 6538	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Staphylococcus aureus</i> ATCC 25923	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Candida albicans</i> ATCC 2091	luxuriant	≤5 d	50 -100	30 -35 °C
<i>Streptococcus pneumoniae</i> ATCC 6305	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Pseudomonas aeruginosa</i> ATCC 27853	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Salmonella</i> Typhimurium ATCC 14028	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Salmonella</i> Abony NCTC 6017	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Bacillus subtilis</i> ATCC 6633	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Micrococcus luteus</i> ATCC 9341	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Escherichia coli</i> NCTC 9002	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Pseudomonas aeruginosa</i> ATCC 9027	luxuriant	18 -24 hrs	50 -100	30 -35 °C

**Sterility Testing- Growth promotion+Validation**

<i>Micrococcus luteus</i> ATCC 9341	luxuriant	<=3 d	50 -100	20 -25 °C
<i>Salmonella Abony</i> NCTC 6017	luxuriant	<=3 d	50 -100	20 -25 °C
<i>Candida albicans</i> ATCC 10231	luxuriant	<=5 d	50 -100	30 -35 °C
* <i>Aspergillus brasiliensis</i> ATCC 16404	luxuriant	<=5 d	50 -100	30 -35 °C
<i>Escherichia coli</i> ATCC 8739	luxuriant	<=3 d	50 -100	20 -25 °C
<i>Escherichia coli</i> ATCC 25922	luxuriant	<=3 d	50 -100	20 -25 °C
<i>Escherichia coli</i> NCTC 9002	luxuriant	<=3 d	50 -100	20 -25 °C
<i>Bacillus subtilis</i> ATCC 6633	luxuriant	<=3 d	50 -100	20 -25 °C
<i>Salmonella</i> Typhimurium ATCC 14028	luxuriant	<=3 d	50 -100	20 -25 °C
<i>Streptococcus pneumoniae</i> ATCC 6305	luxuriant	<=3 d	50 -100	20 -25 °C
<i>Staphylococcus aureus</i> ATCC 6538	luxuriant	<=3 d	50 -100	20 -25 °C
<i>Staphylococcus aureus</i> ATCC 25923	luxuriant	<=3 d	50 -100	20 -25 °C
<i>Pseudomonas aeruginosa</i> ATCC 9027	luxuriant	<=3 d	50 -100	20 -25 °C
<i>Pseudomonas aeruginosa</i> ATCC 27853	luxuriant	<=3 d	50 -100	20 -25 °C

\* Key: Formerly known as *Aspergillus niger*

**Reference**

1. MacFaddin J. F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. 1, Williams & Wilkins, Baltimore, M.d.
2. The United States Pharmacopeia, 2008, USP31/NF26, The United States Pharmacopeial Convention, Rockville, MD.
3. Indian Pharmacopeia, 2007, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.
4. Forbes B. A., Sahm D. F. and Weissfeld A. S., 1998, Bailey & Scotts Diagnostic Microbiology, 10th Ed., Mosby, Inc. St. Louis, Mo.

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