



# Technical Data

## Soyabean Casein Digest HiCynth™ Medium (Tryptone Soya HiCynth™ Broth)

MCD011

### Intended Use:

Recommended as a general purpose medium used for cultivation of a wide variety of microorganisms and recommended for sterility testing of moulds and lower bacteria.

### Composition\*\*

| Ingredients                    | Gms / Litre |
|--------------------------------|-------------|
| HiCynth™ Peptone No.3*         | 17.000      |
| HiCynth™ Peptone No.5*         | 3.000       |
| Sodium chloride                | 5.000       |
| Dextrose (Glucose)             | 2.500       |
| Dipotassium hydrogen phosphate | 2.500       |
| Final pH ( at 25°C)            | 7.3±0.2     |

\*\*Formula adjusted, standardized to suit performance parameters

\*Chemically defined peptones

### Directions

Suspend 30.0 grams in 1000 ml purified/ distilled water. Heat if necessary to dissolve the medium completely. Mix well and dispense in tubes or flasks as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes.

*Note: If any fibres are observed in the solution, it is recommended to filter the solution through a 0.22 micron filter to eliminate the possibility of presence of fibres.*

### Principle And Interpretation

Soyabean Casein Digest Medium is recommended by various pharmacopeias as a sterility testing and as a microbial limit testing medium (2,5,6 ). This medium is a highly nutritious medium used for cultivation of a wide variety of organisms (1).Soyabean Casein Digest HiCynth™ Medium is the modification of the same using chemically defined peptone free from animal and vegetable peptones to avoid BSE/TSE/GMO risks associated with animal peptones.

HiCynth™ peptone No. 3 and HiCynth™ peptone No. 5 provides nitrogen and carbon source, amino acids, long chain peptides and vitamins for the growth of microorganisms. Dextrose/glucose serve as the carbohydrate source and dibasic potassium phosphate buffer the medium. Sodium chloride maintains the osmotic balance of the medium.

### Type of specimen

Pharmaceutical samples, Clinical samples - Blood samples.

### Specimen Collection and Handling

For clinical samples, follow appropriate techniques for handling specimens as per established guidelines (3,4).

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (5).

After use, contaminated materials must be sterilized by autoclaving before discarding.

### Warning and Precautions

In Vitro diagnostic Use. 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 clinical specimens. Safety guidelines may be referred in individual safety data sheets.

### Limitations

**Please refer disclaimer Overleaf.**

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 homogeneous free flowing powder

### Colour and Clarity of prepared medium

Light yellow coloured clear solution without any precipitate.

### Reaction

pH of 3.0% w/v aqueous solution at 25°C (after sterilization), pH : 7.3±0.2

### pH

7.10-7.50

### 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 not more than 100 cfu (at 30-35°C for 18-24 hours for bacteria and 5days for fungal) Growth promotion is carried out as per USP/EP/BP/JP/IP.

| Organism                                                              | Inoculum (CFU) | Growth    | Incubation period | Incubation temperature |
|-----------------------------------------------------------------------|----------------|-----------|-------------------|------------------------|
| <i>Salmonella Typhimurium</i> ATCC 14028 (00031*)                     | 50 -100        | luxuriant | 18 -24 hrs        | 30 -35 °C              |
| <i>Salmonella Abony NCTC 6017</i> (00029*)                            | 50 -100        | luxuriant | 18 -24 hrs        | 30 -35 °C              |
| <i>Pseudomonas aeruginosa</i> ATCC 9027 (00026*)                      | 50 -100        | luxuriant | 18 -24 hrs        | 30 -35 °C              |
| <i>Streptococcus pneumoniae</i> ATCC 6305                             | 50 -100        | luxuriant | 18 -24 hrs        | 30 -35 °C              |
| <i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 6538 (00032*)  | 50 -100        | luxuriant | 18 -24 hrs        | 30 -35 °C              |
| <i>Escherichia coli</i> ATCC 25922 (00013*)                           | 50 -100        | luxuriant | 18 -24 hrs        | 30 -35 °C              |
| <i>Escherichia coli</i> NCTC 9002                                     | 50 -100        | luxuriant | 18 -24 hrs        | 30 -35 °C              |
| <i>Escherichia coli</i> ATCC 8739 (00012*)                            | 50 -100        | luxuriant | 18 -24 hrs        | 30 -35 °C              |
| <i>Bacillus subtilis</i> subsp. <i>spizizenii</i> ATCC 6633 (00003*)  | 50 -100        | luxuriant | 18 -24 hrs        | 30 -35 °C              |
| <i>Micrococcus luteus</i> ATCC 9341                                   | 50 -100        | luxuriant | 18 -24 hrs        | 30 -35 °C              |
| <i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)                     | 50 -100        | luxuriant | 18 -24 hrs        | 30 -35 °C              |
| <i>Candida albicans</i> ATCC 10231 (00054*)                           | 50 -100        | luxuriant | <=5 d             | 20 -25 °C              |
| <i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923 (00034*) | 50 -100        | luxuriant | 18 -24 hrs        | 30 -35 °C              |
| <b>Sterility Testing- Growth promotion+Validation</b>                 |                |           |                   |                        |
| <i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 6538 (00032*)  | 50 -100        | luxuriant | <=3 d             | 20 -25 °C              |

Please refer disclaimer Overleaf.

|                                                                             |         |           |       |           |
|-----------------------------------------------------------------------------|---------|-----------|-------|-----------|
| # <i>Aspergillus brasiliensis</i><br>ATCC 16404 (00053*)                    | 50 -100 | luxuriant | <=5 d | 20 -25 °C |
| <i>Candida albicans</i> ATCC<br>2091 (00055*)                               | 50 -100 | luxuriant | <=5 d | 30 -35 °C |
| <i>Staphylococcus aureus</i><br>subsp. <i>aureus</i> ATCC<br>25923 (00034*) | 50 -100 | luxuriant | <=3 d | 20 -25 °C |
| <i>Escherichia coli</i> ATCC<br>25922 (00013*)                              | 50 -100 | luxuriant | <=3 d | 20 -25 °C |
| <i>Pseudomonas aeruginosa</i><br>ATCC 9027 (00026*)                         | 50 -100 | luxuriant | <=3 d | 20 -25 °C |
| <i>Bacillus subtilis</i> subsp.<br><i>spizizenii</i><br>ATCC 6633 (00003*)  | 50 -100 | luxuriant | <=3 d | 20 -25 °C |
| <i>Salmonella Typhimurium</i><br>ATCC 14028 (00031*)                        | 50 -100 | luxuriant | <=3 d | 20 -25 °C |
| <i>Salmonella Abony</i> NCTC<br>6017 (00029*)                               | 50 -100 | luxuriant | <=3 d | 20 -25 °C |
| <i>Streptococcus pneumoniae</i><br>ATCC 6305                                | 50 -100 | luxuriant | <=3 d | 20 -25 °C |
| <i>Escherichia coli</i><br>ATCC 8739 (00012*)                               | 50 -100 | luxuriant | <=3 d | 20 -25 °C |
| <i>Escherichia coli</i> NCTC 9002                                           | 50 -100 | luxuriant | <=3 d | 20 -25 °C |
| <i>Pseudomonas aeruginosa</i><br>ATCC 27853 (00025*)                        | 50 -100 | luxuriant | <=3 d | 20 -25 °C |
| <i>Micrococcus luteus</i> ATCC<br>9341                                      | 50 -100 | luxuriant | <=3 d | 20 -25 °C |

Key : (#) Formerly known as *Aspergillus niger*, (\*) Corresponding WDCM numbers

## Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 15-25°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. 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 clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (3,4).

## Reference

1. Forbes B. A., Sahm D. F. and Weissfeld A. S., 1998, Bailey & Scotts Diagnostic Microbiology, 10th Ed., Mosby, Inc. St. Louis, Mo.
2. Indian Pharmacopeia, 2018, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.
3. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
4. 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.
5. MacFaddin J. F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. 1, Williams & Wilkins, Baltimore, M.d.
6. The United States Pharmacopeia, 2019, The United States Pharmacopeial Convention, Rockville, MD.

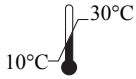
Revision : 03 / 2019



In vitro diagnostic medical device



CE Marking



Storage temperature



Do not use if package is damaged



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