



## Sabouraud Dextrose Broth

LQ120D

### Intended use

Recommended for the enrichment of *Candida albicans* from pharmaceutical products in accordance with the microbial limit testing by harmonized methodology of USP/EP/BP/JP & IP.

### Composition\*\*

Ingredients	g / L
Dextrose (Glucose)	20.000
Mixture of Peptone and Tryptone (1:1)#	10.000
pH after sterilization ( at 25°C)	5.6±0.2

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

# Mixture of Peptic digest of animal tissue and Pancreatic digest of casein (1:1)

### Directions

Label the ready to use LQ120D bottle. Inoculate the sample and Incubate at specified temperature and time.

### Principle And Interpretation

Fungi were among the first microorganisms recognized because some of the fruiting structures, such as the mushrooms, are large enough to be seen without a microscope. Fungi can be grouped simply on the basis of morphology as either yeasts or moulds (1). Fungal diseases that occur on the skin, hair and mucous membrane are called superficial mycoses, and the organism that cause them, the dermatophytes (2). Where fungi are to be isolated, it is good practice to use a medium that favors their growth but is not optimal for the growth of bacteria.

Sabouraud Dextrose Broth is a modification of Dextrose Agar described by Sabouraud (3). It is useful for the cultivation of fungi. This medium is in accordance with the harmonized method of USP/EP/BP/JP/IP (4-8) and is recommended for microbiological examination of non-sterile products.

Peptone and Tryptone provides nitrogenous, carbonaceous compounds, long chain amino acids and other essential for the growth of fungi. Dextrose (Glucose) acts as the energy source.

### Type of specimen

Pharmaceutical samples

### Specimen Collection and Handling

For pharmaceutical samples, follow appropriate techniques for handling specimens as per established guidelines (4-8).

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. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.
2. Further biochemical and serological tests should be carried out for complete identification.
3. Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.

### 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

Sterile clear Sabouraud Dextrose Broth in bottle

**Colour of Medium**

Light amber coloured clear solution

**Quantity of Medium**

500 ml of medium in glass bottle

**pH**

5.40-5.80

**Sterility Check**

Passes release criteria

**Growth Promotion Test**

Growth Promotion was observed in accordance with the harmonized method of USP/EP/BP/JP after an incubation at 30-35°C for 3-5 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 100 cfu (at 30-35°C for 3-5 days).

**Cultural Response**

Cultural characteristics observed after incubation at 20-25 °C for 3-5 days.

Organism	Inoculum (CFU)	Growth	Incubation temperature	Incubation period
<i>Candida albicans</i> ATCC 10231 (00054*)	50 -100	luxuriant	30 -35 °C	<=3 d

**Growth Promotion + Total Yeast and Mould count**

<i>Candida albicans</i> ATCC 10231 (00054*)	50 -100	luxuriant	20 -25 °C	<=5 d
# <i>Aspergillus brasiliensis</i> ATCC 16404 (00053*)	50 -100	luxuriant	20 -25 °C	<=5 d

Key: (\*) Corresponding WDCM numbers

(#) Formerly known as *Aspergillus niger*

**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 (9,10).

**Reference**

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