

PRODUCT SPECIFICATION

**TRYPTONE SOYA AGAR**

**BO0330V**

**Typical Formula\***

	grams per litre
Pancreatic digest of casein	15.0
Enzymatic digest of soya bean	5.0
Sodium chloride	5.0
Agar	15.0

\*adjusted as required to meet performance standards

**Preparation**

Suspend Tryptone Soya Agar (40 grams / litre) in de-ionised water. Heat to dissolve. Cool and dispense 500ml into final containers, 500ml sirop bottles. Sterilise at 121°C for 15 minutes. When cool, label each bottle and pack in units of 10 into labelled boxes.

**Format**

Ten sirop bottles with screw cap closures in a box.

**Labels**

Label gives details of product name, product code, recommended storage temperature, lot number and expiry date.

**Physical Characteristics**

pH	7.3 ± 0.2
Colour	Straw 1, Straw 1-2, Straw 2
Clarity	clear
Fill weight	500-504g

**Packaging and presentation**

General appearance of bottle and label should be satisfactory. Label data should be correct.

**Contamination Check**

Macroscopic examination should show no evidence of microbial growth after incubation at 20 - 24°C and 30 - 34°C for 5 days.

**Microbiological Tests Using Optimum Inoculum Dilution**

**(Microbiology is conducted after the agar has been melted by autoclaving at 100°C for 30 minutes, cooled to 45-50°C, then dispensed into Petri dishes and allowed to set).**

**Results after incubation at 30-35°C for up to 3 days**

Positive controls

Inoculum 10-100 colony forming units.

<i>Escherichia coli</i>	ATCC® 8739	Cream colonies
<i>Staphylococcus aureus</i>	ATCC® 6538	Straw colonies
<i>Bacillus subtilis</i>	ATCC® 6633	Irregular, straw colonies
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	Straw colonies
<i>Candida albicans</i>	ATCC® 10231	Cream colonies
<i>Aspergillus brasiliensis</i>	ATCC® 16404	White mycelia with or without black spores

## Results after incubation at 20-25°C for up to 5 days

<i>Candida albicans</i>	ATCC® 10231	Cream colonies
<i>Aspergillus brasiliensis</i>	ATCC® 16404	White mycelia with black spores

Colony counts shall be  $\geq 70\%$  of the control medium (Tryptone Soya Agar or Sabouraud Dextrose Agar)

Tested in accordance with the harmonised methods described in the current European, United States and Japanese pharmacopoeia for the microbiological examination of non-sterile products, microbial enumeration tests.

### Storage conditions

Store away from light between 2-25°C.

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