

**TRYPTONE SOYA BROTH (ACCORDING TO EP/USP)**

**BO0351Y**

**Typical Formula\***

	grams per litre
Pancreatic digest of casein	17.0
Papaic digest of soybean meal	3.0
Sodium chloride	5.0
Dibasic potassium phosphate	2.5
Glucose	2.5

\*adjusted as required to meet performance standards

**Preparation**

Suspend Tryptone Soya Broth (30.0 grams / litre) in de-ionised water. Heat to dissolve. Cool and dispense 4ml into final containers, universal bottles. Sterilise at 121°C for 15 minutes. When cool, label each bottle and pack in units of 24 into labelled boxes.

**Format**

Twenty four universal 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 2, Straw 2-3 or Straw 3
Clarity	Clear
Fill weight	4.0g – 4.3g

**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 14 days.

**Microbiological Tests Using Optimum Inoculum Dilution**

Positive controls

Inoculum 10-100 colony forming units.

**Results after incubation at 30-35°C for up to 2 days**

<i>Escherichia coli</i>	ATCC® 8739	Turbid growth
<i>Staphylococcus aureus</i>	ATCC® 6538	Turbid growth
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	Turbid growth

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

<i>Bacillus subtilis</i>	ATCC® 6633	Turbid growth
<i>Salmonella</i> Typhimurium	ATCC® 14028	Turbid growth

Tested in accordance with the harmonised methods described in the European, United States and Japanese pharmacopoeias for sterility tests.

### Results after incubation at 20-25°C for up to 3 days

<i>Bacillus subtilis</i>	ATCC® 6633	Flocculent / surface growth
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### Results after incubation at 20-25°C for 5 days

<i>Candida albicans</i>	ATCC® 10231	Flocculent / surface growth
<i>Aspergillus brasiliensis</i>	ATCC® 16404	White mycelia, with or without black spores

Tryptone Soya Agar and Sabouraud Dextrose Agar are used as the control media to determine the inoculum.

Clearly visible growth within 3 days for bacteria and within 5 days for fungi

### Storage conditions

Store away from the light between 2 – 25°C.

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