

PRODUCT SPECIFICATION**TRYPTONE SOYA AGAR
(TRIPLE WRAPPED AND IRRADIATED)****PO0821B****Typical Formula***

	grams per litre
Tryptone	15.0
Soya peptone	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. Sterilise at 121°C for 15 minutes. Cool and aseptically dispense into Petri dishes. Label dishes, wrap and label pack. Irradiate at 8 - 20kGy.

Format

Ten 90mm plates, wrapped in one nylon and two cellulose-based film wraps. An irradiation indicator sticker is applied, to confirm irradiation status. Each plate is ink-jet printed with (abbreviated) product name, product code, lot number and expiry date.

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	22.0-23.5g
Irradiation dose	8 - 20 kGy

Packaging and presentation

General appearance of packaging 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 DilutionPositive controls**Results after incubation at 30 - 35°C for up to 3 days**

Inoculum 10 - 100 colony forming units

<i>Staphylococcus aureus</i>	ATCC® 6538	Straw colonies
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	Straw colonies
<i>Escherichia coli</i>	ATCC® 8739	Cream colonies

PRODUCT SPECIFICATION

Bacillus subtilis ATCC® 6633 Irregular, straw colonies

Results after incubation at 30-35°C 5 days

Inoculum 10 - 100 colony forming units

Candida albicans ATCC® 10231 Cream colonies
Aspergillus brasiliensis ATCC® 16404 White mycelia, black spores

Colony counts shall be equal to or greater 70% of the control medium. (Tryptone Soya Agar or Sabouraud Dextrose Agar)

Results after incubation at 20-25°C 3 days

Bacillus subtilis ATCC® 6633 Irregular, straw colonies

Results after incubation at 20-25°C 5 days

Candida albicans ATCC® 10231 Cream colonies
Aspergillus brasiliensis ATCC® 16404 White mycelia, black spores

Colony counts shall be equal to or greater 50% of the control medium. (Tryptone Soya Agar or Sabouraud Dextrose Agar)

Tested in accordance with the methods described in the current United States pharmacopoeia for the microbiological control and monitoring of aseptic processing environments.

Storage conditions

Store away from the light between 2 - 25°C

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