

PRODUCT SPECIFICATION

TRYPTONE SOYA AGAR
(TRIPLE WRAPPED AND IRRADIATED)

PO0306T

Typical Formula*

| | grams per litre |
|-----------------|-----------------|
| Tryptone | 15.0 |
| Soya peptone | 5.0 |
| Sodium chloride | 5.0 |
| Agar | 15.0 |

Addition

| | |
|----------------|-----|
| Agar Technical | 5.0 |
|----------------|-----|

*Adjusted as required to meet performance standards

Preparation

Suspend Tryptone Soya Agar (40 grams / litre) and Agar Technical (5 grams/ litre) in de-ionised water. Sterilise at 121°C for 15 minutes. Cool and aseptically dispense into 140mm dishes. Label dishes, wrap and label pack. Irradiate at 8 - 20kGy.

Format

Five 140mm plates, wrapped in three nylon 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 | 88.0g – 95.0g |
| Irradiation dose | 8 - 20 kGy |

Packaging and presentation

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

Contamination Check (tests carried out post-irradiation)

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

Positive controls

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

Inoculum 10 - 100 colony forming units

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| | | |
|-------------------------------|------------|---------------------------|
| <i>Staphylococcus aureus</i> | ATCC® 6538 | Straw colonies |
| <i>Pseudomonas aeruginosa</i> | ATCC® 9027 | Straw colonies |
| <i>Bacillus subtilis</i> | ATCC® 6633 | Irregular, straw colonies |
| <i>Escherichia coli</i> | ATCC® 8739 | Cream colonies |

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

Inoculum 10 - 100 colony forming units

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

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

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

| | | |
|--------------------------|------------|---------------------------|
| <i>Bacillus subtilis</i> | ATCC® 6633 | Irregular, straw colonies |
|--------------------------|------------|---------------------------|

Colony counts shall be equal to or greater than 50% of the control medium. (Tryptone Soya 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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