

## OXOID PRODUCT SPECIFICATION

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

**BO0351R**

### 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             |

### Preparation

Suspend Tryptone Soya Broth (30 grams / litre) in de-ionised water. Heat to dissolve. Cool and dispense 200ml into final containers, 250ml 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

#### Physical Tests

|             |               |
|-------------|---------------|
| pH          | 7.3 ± 0.2     |
| Colour      | Straw         |
| Clarity     | Clear         |
| Fill weight | 200.0g + 4.0g |

### Packaging and presentation:

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

### Sterility Test

Macroscopic examination should show no evidence of microbial growth after incubation at 20-24C 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 30-34°C for 36-48 hours.

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

### Results after incubation at 21-25°C for up to 3 days

|                          |            |                             |
|--------------------------|------------|-----------------------------|
| <i>Bacillus subtilis</i> | ATCC® 6633 | Flocculent / surface growth |
|--------------------------|------------|-----------------------------|

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

|                               |             |               |
|-------------------------------|-------------|---------------|
| <i>Bacillus subtilis</i>      | ATCC® 6633  | Turbid growth |
| <i>Salmonella typhimurium</i> | ATCC® 14028 | Turbid growth |

### Results after incubation at 21-25°C for 5 days.

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

### Storage conditions

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

The Microbiological Quality Control of this product complies with the following Pharmacopoeiae;  
British Pharmacopoeia 2005  
European Pharmacopoeia 6<sup>th</sup> Edition 2008  
The Japanese Pharmacopoeia JP 15 2006  
The United States Pharmacopoeia USP 31 2008