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BT-SPEC-0024
OXOID QUALITY ASSURANCE
PRODUCT SPECIFICATION

COLD FILTERABLE TRYPTONE SOYA BROTH IN BIO-PROCESS CONTAINER

BP1065A (1 Litre)
BP1065C (10 Litres)
BP1065E (20 Litres)

BP1065

Typical Formula*

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

* adjusted as required to meet performance standards

Directions

This product is ready prepared.

Packaging and Presentation

This product is presented as a Bio-Process Container (BPC) filled with liquid media. The BPC is fitted with two tubes with one connection point each. The general appearance of the BPC and connections should be satisfactory.

Storage Conditions

Store at 2-8°C

Physical Characteristics

Colour - straw liquid
Clarity - clear
pH 7.3 ± 0.2 at 25°C

Sterility Test

Macroscopic examination should show no evidence of microbial growth after incubation at 20-25°C and 30-35°C for 14 days.

Microbiological Tests Using Optimum Inoculum Dilution

Control Media : Tryptone Soya Agar or Sabouraud Dextrose Agar, where appropriate

Medium is challenged with 10-100 colony forming units/10ml

Reactions after incubation at 30-35°C for 24 hours

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

Reactions after incubation at 20-25°C for 48 hours

<i>Bacillus subtilis</i>	ATCC® 6633	Turbid growth
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Reactions after incubation at 20-25°C for 5 days

<i>Candida albicans</i>	ATCC® 10231	Turbid growth
<i>Aspergillus brasiliensis</i>	ATCC® 16404	Visible growth

A satisfactory result is represented by visible growth.

The Microbiological Quality Control of this product complies with the following current pharmacopoeia;

British Pharmacopoeia

European Pharmacopoeia

The Japanese Pharmacopoeia

The United States Pharmacopoeia