OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION

COLD FILTERABLE TRYPTONE SOYA BROTH CM1065

COLD FILTERABLE TRYPTONE SOYA BROTH (TSB) **CM1065**

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 not suitable for use as a product placebo in dry powder fill trials. This product has received a dose of Gamma-irradiation at 30 – 70 kGy. To prepare the medium dissolve 30g in 1 litre of distilled water. Mix well and sterilize by filtration or by autoclaving at 121°C for 15 minutes.

Physical Characteristics

Straw, free-flowing powder
Colour on reconstitution - straw 2-3
Moisture level - less than 7%
pH 7.3 ± 0.2 at 25°C (post autoclaving and post filtration)
Clarity - clear

Vcap - Polyvinylidene fluoride - equal to or greater than 3,920/47mm disc
(equivalent to or greater than 2,800 litres/m²)
Vcap - Polyethersulfone - equal to or greater than 3,920/47mm disc
(equivalent to or greater than 2,800 litres/m²)
Vcap - Nylon - equal to or greater than 3,920/47mm disc
(equivalent to or greater than 2,800 litres/m²)

Sterility of powder (post irradiation) - no evidence of microbial growth after incubation in Tryptone Soya Broth (CM0129) and Fluid Thioglycollate Medium (CM0173) for 14 days at 20-25°C and 30-35°C.

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Microbiological Tests Using Optimum Inoculum Dilution

Control Media: Tryptone Soya Agar, Columbia Blood Agar Base enriched with 5% v/v horse blood or Sabouraud Dextrose Agar, where appropriate

Tested in accordance with current USP/EP/BP/JP

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

Medium is challenged with 10-100 colony-forming units

Escherichia coli	ATCC® 8739	Turbid growth
Staphylococcus aureus	ATCC® 6538	Turbid growth
Pseudomonas aeruginosa	ATCC® 9027	Turbid growth
Salmonella abony	NCTC 6017	Turbid growth
Salmonella typhimurium	ATCC® 14028	Turbid growth

A satisfactory result is represented by visible growth.

Reactions after incubation at 30-35°C for 3 days

Medium is challenged with 10-100 colony-forming units

Kocuria rhizophila	ATCC® 9341	Turbid growth

A satisfactory result is represented by visible growth.

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

Medium is challenged with 10-100 colony-forming units

Bacillus subtilis	ATCC® 6633	Flocculent/surface growth
Candida albicans	ATCC® 10231	Flocculent/surface growth

A satisfactory result is represented by visible growth.

Reactions after incubation at 20-25°C for 5 days

Medium is challenged with 10-100 colony-forming units

Aspergillus brasiliensis	ATCC® 16404	White mycelia, black spores / no spores

A satisfactory result is represented by visible growth.

The Microbiological Quality Control of this product complies with the following current pharmacopoeia;
The United States Pharmacopoeia
European Pharmacopoeia
British Pharmacopoeia
The Japanese Pharmacopoeia

Validation was completed on media sterilized by both filtration and autoclaving at 121°C for 15 minutes.

Routine microbiological testing is carried out on media sterilized at 121°C for 15 minutes.

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Revision History

Section / Step	Description of Change	Reason for Change	Reference
Entire Document	Update to new document template Update to specification	Change control	BT-CC-1475