BT-SPEC-0141

Page 1 of 3

OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION

THIOGLYCOLLATE BROTH USP ALTERNATIVE (CM0391)

THIOGLYCOLLATE BROTH USP ALTERNATIVE Typical Formula*		CM0391
Yeast extract	grams per litre	5.0
Pancreatic digest of casein		15.0
Glucose		5.5
Sodium thioglycollate		0.5
Sodium chloride		2.5
L-Cystine		0.5

^{*} adjusted as required to meet performance standards

Directions

Suspend 29g in 1 litre of distilled water. Bring to the boil to dissolve completely. Mix well and distribute into final containers. Sterilize by autoclaving at 121°C for 15 minutes. Prepare freshly or boil and cool the medium just before use.

Physical Characteristics

Straw, free-flowing powder
Colour on reconstitution - straw 1-2
Moisture level - less than 7%
pH 7.1 ± 0.2 at 25°C
Clarity - clear
Standing test - passes test



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BT-SPEC-0141

Page 2 of 3

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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.

Prepare medium in 20ml volumes in 150 x 24mm test tubes with aluminium caps.

Tested in accordance with USP/EP/BP/JP

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

Medium is challenged with 10-100 colony-forming units

Staphylococcus aureus	ATCC® 6538	Turbid growth and/or single colonies
Kocuria rhizophila	ATCC® 9341	Turbid growth and/or single colonies
Pseudomonas aeruginosa	ATCC® 9027	Turbid growth and/or single colonies
Clostridium sporogenes	ATCC® 19404	Turbid growth and/or single colonies
Clostridium sporogenes	ATCC® 11437	Turbid growth and/or single colonies
Bacteroides vulgatus	ATCC® 8482	Turbid growth and/or single colonies

Reactions after incubation at 20-25°C for 3 days

Medium is challenged with 10-100 colony-forming units

Bacillus subtilis ATCC® 6633 Turbid growth and/or single colonies

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

Medium is challenged with 10-100 colony-forming units

Candida albicans ATCC® 10231 Flocculent growth

Aspergillus brasiliensis ATCC® 16404 White mycelia with or without black spores

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



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BT-SPEC-0141

Page 3 of 3

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The United States PharmacopoeiaRevision History

Description of Change	Reason for Change	Reference
Reformatting to new template	Change control	BT-CC-1482
Addition of 'Tested in accordance with' statement		
	Reformatting to new template	Reformatting to new template Addition of 'Tested in