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OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION		
TRYPTONE SOYA BROTH (CM0129)		

TRYPTONE SOYA BROTH

CM0129

Typical Formula*

Pancreatic digest of casein	grams per litre	17.0
Enzymatic** digest of soya bean		3.0
Sodium chloride		5.0
Di-potassium hydrogen phosphate		2.5
Glucose		2.5

** contains papain

* adjusted as required to meet performance standards

Directions

Dissolve 30g in 1 litre of water (purified, as required) and distribute into final containers. Sterilize 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

Clarity - clear

Thermophiles and mesophiles shall be absent after incubation at 55°C and 37°C for 3 days.

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Microbiological Tests Using Optimum Inoculum Dilution

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

Reactions after incubation at 30-35°C for 18-24 hours

Medium is challenged with 10-100 colony-forming units

<i>Streptococcus pyogenes</i>	ATCC® 19615	Turbid growth
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A satisfactory result is represented by visible growth.

Tested in accordance with current CLSI M22 A

Reactions after incubation at 33-37°C for 18-24 hours

Medium is challenged with 1E+04 to 1E+06 colony-forming units

<i>Escherichia coli</i>	ATCC® 25922	Turbid growth
<i>Staphylococcus aureus</i>	ATCC® 25923	Turbid growth

A satisfactory result is represented by visible growth.

Reactions after incubation at 33-37°C for 5 days

Medium is challenged with 1E+04 to 1E+06 colony-forming units

<i>Streptococcus pneumoniae</i>	ATCC® 6305	Turbid growth
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A satisfactory result is represented by visible growth.

Reactions after incubation at 33-37°C for 5 days under anaerobic conditions (for details refer to Oxoid Manual - Atmosphere Generation Systems)

Medium is challenged with 1E+04 to 1E+06 colony-forming units

<i>Bacteroides fragilis</i>	ATCC® 25285	Turbid growth
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A satisfactory result is represented by visible growth.

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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

<i>Escherichia coli</i>	ATCC® 8739	Turbid growth
<i>Staphylococcus aureus</i>	ATCC® 6538	Turbid growth
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	Turbid growth
<i>Salmonella abony</i>	NCTC 6017	Turbid growth
<i>Salmonella typhimurium</i>	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

<i>Bacillus subtilis</i>	ATCC® 6633	Flocculent/surface growth
<i>Kocuria rhizophila</i>	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

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

A satisfactory result is represented by visible growth.

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


Medium is challenged with 10-100 colony-forming units

<i>Aspergillus brasiliensis</i>	ATCC® 16404	White mycelia, black spores / no spores
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A satisfactory result is represented by visible growth.

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

1. European Pharmacopoeia: Current version.
 - 2.6.12 Microbiological Examination of Non-Sterile Products: Harmonised Method: Microbial Enumeration tests
 - 2.6.13 Microbiological Examination of Non-Sterile Products: Tests for Specified Microorganisms. B. Harmonised Method
2. United States Pharmacopoeia: Current version.
 - 61 Microbiological Examination of Non-Sterile Products: Microbial Enumeration tests.
 - 62 Microbiological Examination of Non-Sterile Products: Tests for Specified Microorganisms
3. Japanese Pharmacopoeia: Current version.

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Revision History

Section / Step	Description of Change	Reason for Change	Reference
N/A	Addition of CLSI testing Update to USP/EP/BP/JP testing	Change control	BT-CC-1475