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OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION		
SODIUM CHLORIDE PEPTONE BROTH (CM0982)		

SODIUM CHLORIDE PEPTONE BROTH

CM0982

(Buffered sodium chloride-peptone solution pH 7.0)**

** EP, USP, JP, BP

Typical Formula*

Potassium dihydrogen phosphate	grams per litre	3.56
Di-sodium hydrogen phosphate		5.77†
Sodium chloride		4.3
Peptone (meat)		1.0

† 5.77g of di-sodium hydrogen phosphate are equivalent to 7.2g of di-sodium hydrogen phosphate dihydrate


* adjusted as required to meet performance standards

Directions

Dissolve 14.63g in 1 litre of water (purified as required). Mix well and distribute into final containers. Sterilize by autoclaving at 121°C for 15 minutes.

Physical Characteristics

Straw, free-flowing powder
 Colour on reconstitution - straw 1
 Moisture level - less than 7%
 pH 7.0 ± 0.2 at 25°C
 Clarity - clear

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Microbiological Tests Using Optimum Inoculum Dilution

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

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

Tested as a diluent

Inoculate the medium with the test organism. At time zero and after holding at room temperature (15-25°C) for 2 hours, subculture onto an appropriate control medium.

Medium is challenged with 10⁷-77 colony-forming units

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

<i>Escherichia coli</i>	ATCC® 8739	1-3mm cream colonies
<i>Staphylococcus aureus</i>	ATCC® 6538	0.5-1mm straw colonies
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	1-4mm straw colonies
<i>Bacillus subtilis</i>	ATCC® 6633	1-3mm irregular, straw colonies
<i>Salmonella typhimurium</i>	ATCC® 14028	1-3mm cream colonies
<i>Salmonella abony</i>	NCTC 6017	1-3mm cream colonies

Reactions after incubation at 30-35°C for 24-48 hours under anaerobic conditions (for details, refer to Oxoid Manual - Atmosphere Generation Systems)

<i>Clostridium sporogenes</i>	ATCC® 11437	1-3mm pale straw colonies
<i>Clostridium sporogenes</i>	ATCC® 19404	1-3mm pale straw colonies


Reactions after incubation at 20-25°C for 2-3 days

<i>Candida albicans</i>	ATCC® 10231	1-3mm cream colonies
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Reactions after incubation at 20-25°C for 5-7 days

<i>Aspergillus brasiliensis</i>	ATCC® 16404	>10mm white mycelia, black spores
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A satisfactory result is represented by recovery of ± 30% of the Control cfu (0 minutes) from an inoculum of 10⁷-77 cfu after holding at room temperature (15-25°C) for 2 hours. An initial inoculum of less than 77 colony-forming units will ensure a final level of less than 100 cfu.

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Equivalent results are obtained after holding medium at 2-8°C for 18-24 hours.

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.

Revision History

Section / Step	Description of Change	Reason for Change	Reference
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Entire Document	Reformatting to new template Update to test specification	Change control	BT-CC-1500
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