

Technical Data Sheet

GranuCult™

Sodium Chloride Peptone Broth (Buffered)

acc. EP, USP, JP

Ordering number: 1.10582.0500 / 1.10582.5000

For the dissolving, suspending and diluting of test samples from pharmaceutical and other material and of test strains.

This culture medium complies with the specifications given by the harmonized methods of EP, USP, JP for Microbial Examination of Non-sterile Products: Microbial Enumeration Test and Tests for Specified Microorganisms.

Mode of Action

The combination of phosphate buffer, sodium chloride and peptone increases the viability of sensitive microorganism in particular and osmotic stability with a stable pH. Basic nutrients are supplied by the low peptone content to maintain organisms viability, but does not allow significant growth of more fastidious microorganisms.

Surface-active ingredients or inactivators of antimicrobial agents may be added to this medium, e.g. according to EP, USP, JP.

Typical Composition

Specified by EP, USP, JP		GranuCult™ Sodium Chloride Peptone Broth (Buffered) acc. EP, USP, JP	
KH ₂ PO ₄	3.6 g/l	KH ₂ PO ₄	3.6 g/l
Na ₂ HPO ₄ x 2 H ₂ O	7.2 g/l	Na ₂ HPO ₄ x 2 H ₂ O	7.2 g/l
NaCl	4.3 g/l	NaCl	4.3 g/l
Peptone (Meat or Casein)	3 g/l	Peptone from Meat	1 g/l
Water	1000 ml/l	Water	n/a
pH at 25 °C	7.0 ± 0.2	pH at 25 °C	7.0 ± 0.2

Preparation

Dissolve 16.1 g in 1 l of purified water. If desired distribute into smaller containers; if necessary add 1-10 ml Tween® 20 or Tween® 80 to 1 l of medium, distribute homogeneously.

Autoclave 15 min at 121 °C.

The prepared medium is clear and slightly yellowish to yellowish.

Experimental Procedure and Evaluation

Depend on the purpose for which the medium is used, e.g. follow directions given by EP, USP, JP.

Storage

Store at +15 °C to +25 °C, dry and tightly closed. Do not use clumped or discolored medium. Protect from UV light (including sun light). For *in vitro* use only.

Quality Control

Function	Control strains	Incubation	Reference medium	Method of control	Expected results
Dilution	<i>Escherichia coli</i> ATCC® 8739	45 min at 20-25 °C (room temp.)	Tryptic Soy Agar (TSA)	Quantitative	± 30 % colonies / T ₀ (±30 % of original count, 70-130 %)
	<i>Escherichia coli</i> ATCC® 25922				
	<i>Staphylococcus aureus</i> ATCC® 25923				
	<i>Staphylococcus aureus</i> ATCC® 6538				

Please refer to the actual batch related Certificate of Analysis.

The performance test is in accordance with the current version of EN ISO 11133 and the harmonised method of EP, USP and JP.

Literature

European Directorate for the Quality of Medicines and Healthcare. (2014): The European Pharmacopoeia. 8th Ed. Chapter 2.6.12 Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter 2.6.13 Microbiological examination of non-sterile products: Test for specified products. Strasbourg, France.

ISO International Standardisation Organisation. Microbiology of food, animal feed and water - Preparation, production, storage and performance testing of culture media. EN ISO 11133:2014.

Japanese Ministry of Health, Labour and Welfare. (2011): The Japanese Pharmacopoeia. 16th Ed. Chapter 4.05 Microbial Limit Test I. Microbiological examination of non-sterile products: Total viable aerobic count and II. Microbiological examination of non-sterile products: Test for specified products. Japanese Ministry of Health, Labour and Welfare. Tokyo, Japan.

United States Pharmacopeial Convention. (2014): The United States Pharmacopeia 38/National Formulation 33, Supp. 2. Chapter <61> Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter <62> Microbiological examination of non-sterile products: Test for specified products. Rockville, Md., USA.

Ordering Information

Product	Cat. No.	Pack size
GranuCult™ Sodium Chloride Peptone Broth (Buffered) acc. EP, USP, JP	1.10582.0500	500 g
GranuCult™ Sodium Chloride Peptone Broth (Buffered) acc. EP, USP, JP	1.10582.5000	5 kg
Tween® 20	8.22184.0500	500 ml
Tween® 80	8.22187.0500	500 ml

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