Technical Data Sheet

GranuCult™
Tryptic Soy Agar
acc. EP, USP, JP, ISO and FDA-BAM
Ordering number: 1.05458.0500 / 1.05458.5000

For the isolation and cultivation of a wide range of microorganisms from different material.

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.

It complies with the specifications given by EN ISO 11133 for the usage as a reference medium during performance testing of culture media and with those given by FDA-BAM and APHA.

Mode of Action

The combination of the two peptones, enzymatic digest of casein and of soy bean provides a high nutrition by supplying organic nitrogen, amino acids and longer-chained peptides. In this complex medium the osmotic balance is supplied by sodium chloride whilst agar-agar is the solidifying agent.

Typical Composition

Specified by EP, USP, JP		**Specified by BAM M152**		**GranuCult™ Tryptic Soy Agar acc. EP, USP, JP, ISO and FDA-BAM**	
Pancreatic Digest of Casein	15 g/l	Trypticase Peptone	15 g/l	Pancreatic Digest of Casein*	15 g/l
Papaic Digest of Soya Bean	5 g/l	Phytone Peptone	5 g/l	Papaic Digest of Soya Bean**	5 g/l
NaCl	5 g/l	NaCl	5 g/l	NaCl	5 g/l
Agar	15 g/l	Agar	15 g/l	Agar-Agar***	15 g/l
Water	1000 ml/l	Water	1000 ml/l	Water	n/a
pH at 25 °C	7.3 ± 0.2	pH at 25 °C	7.3 ± 0.2	pH at 25 °C	7.3 ± 0.2

* Enzymatic digest of casein is equivalent to trypticase peptone ** Papaic digest of soy bean is equivalent to phytone peptone *** Agar-Agar is equivalent to other different terms of agar

Preparation

Dissolve 40 g in 1 l of purified water. Heat in boiling water and agitate frequently until completely dissolved. Autoclave 15 min at 121 °C.

The prepared medium is clear and yellowish-brown.

Experimental Procedure and Evaluation

Depend on the purpose for which the medium is used, e.g. follow directions given by EP, USP, JP or by EN ISO 11133.

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
Productivity	*Staphylococcus aureus* ATCC® 6538	24 h at 30-35 °C	Blood agar	Quantitative	≥ 0.7
	Bacillus subtilis ATCC® 6633				
	Escherichia coli ATCC® 8739				
	Pseudomonas aeruginosa ATCC® 9027				
	Candida albicans ATCC® 10231	up to 5 days at 30-35 °C	Sabouraud Dextrose Agar		≥ 0.5
	Aspergillus brasiliensis (formerly *A. niger*) ATCC® 16404				
	Escherichia coli ATCC® 8739	21-27 h at 36-38 °C	Tryptic Soy Agar (TSA)		≥ 0.7
	Escherichia coli ATCC® 25922				
	Bacillus cereus ATCC® 11778				
	Listeria monocytogenes ATCC® 13932				
	Staphylococcus aureus ATCC® 25923				

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 harmonized method of EP, USP and JP.

A recovery rate of 70 % is equivalent to a productivity value of 0.7. A recovery rate of 50 % is equivalent to a productivity value of 0.5.

Literature

APHA (2015): Compendium of Methods for the Microbiological Examination of Foods. 5th ed. American Public Health Association, Washington, D.C.

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.

FDA-BAM (2013): Chapter No. 12: *Staphylococcus aureus* and Chapter 20A: Inhibitory Substances in Milk. U.S. Food and Drug Administration - Bacteriological Analytical Manual.

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™ Tryptic Soy Agar EP, USP, JP, ISO FDA-BAM	1.05458.0500	500 g
GranuCult™ Tryptic Soy Agar EP, USP, JP, ISO FDA-BAM	1.05458.5000	5 kg
ReadyPlate™ TSA ISO, FDA-BAM, EP+USP	1.46431.0020	20 pcs
ReadyPlate™ TSA ISO, FDA-BAM, EP+USP	1.46431.0100	100 pcs

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