Technical Data Sheet

GranuCult® prime

Tryptic Soy Broth (TSB), Casein-Peptone Soymeal-Peptone (CASO) Broth acc. harm. EP/USP/JP and ISO

Ordering number: 1.05459.0500 / 1.05459.5000 / 1.05459.9025

Tryptic Soy Broth (TSB), Casein-Peptone Soymeal-Peptone (CASO) Broth is a universal culture media free from inhibitors and indicators for the isolation and cultivation of fastidious aerobic bacteria, yeasts and molds.

The medium is used for sterility testing of substances, preparations and products as well as a pre- enrichment broth for the test for specified microorganisms or total viable aerobic count determinations using the MPN method within non-sterile products according to the harmonized methods of EP, USP, JP for Microbial Examination of Non-sterile Products: Microbial Enumeration Test and Tests for Specified Microorganisms.

Typical Composition

Specified by EP, USP, JP		**GranuCult® prime Tryptic Soy Broth Casein-Peptone Soymeal-Peptone (CASO) Broth acc. harm. EP/USP/JP and ISO**	
Pancreatic digest of casein	17 g/l	Pancreatic digest of casein*	17 g/l
Papaic digest of soybean meal	3 g/l	Papaic digest of soybean meal**	3 g/l
Glucose monohydrate	2.5 g/l	D(+)Glucose monohydrate	2.5 g/l
NaCl	5 g/l	NaCl	5 g/l
K_2HPO_4	2.5 g/l	K_2HPO_4	2.5 g/l
Water	1000 ml/l	Water	n/a
pH at 25 °C	7.3 ± 0.2	pH at 25 °C	7.3 ± 0.2

Preparation

Suspend 30 g/l. Autoclave 15 min at 121 °C.

The appearance of the medium is clear and yellowish brown.

The pH value at 25 °C is in the range of 7.1-7.5.

Experimental Procedure and Evaluation

Depend on the purpose for which the media are used.

Incubation: 18-24 h at 30-35 °C aerobically, for up to 5 days for the sterility-test at room temperature.

Storage

The product can be used for sampling until the expiry date if stored upright, protected from light and properly sealed at +15 °C to +25 °C.

After first opening of the bottle the content can be used up to the expiry date when stored dry and tightly closed at +15 °C to +25 °C.

Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121 °C, disinfect, incinerate etc.).

Quality Control

Control Strains	ATCC #	Inoculum CFU	Incubation	Expected Results
Escherichia coli	8739	10-100	18-24 h at 30-35 °C	Visible growth
Staphylococcus aureus	6538	10-100	18-24 h at 30-35 °C	Visible growth
Streptococcus pneumoniae	6301	10-100	18-24 h at 30-35 °C	Visible growth
Bacillus subtilis	6633	10-100	18-24 h at 30-35 °C	Visible growth
			3 days at 20-25 °C	Visible growth
Pseudomonas aeruginosa	9027	10-100	18-24 h at 30-35 °C	Visible growth
Salmonella typhimurium	14028	10-100	18-24 h at 30-35 °C	Visible growth
Staphylococcus aureus	25923	10-100	3 days at 20-25 °C	Visible growth
Staphylococcus epidermidis	12228	10-100	3 days at 20-25 °C	Visible growth
Candida albicans	2091	10-100	5 days at 20-25 °C	Visible growth
Candida albicans	10231	10-100	5 days at 20-25 °C	Visible growth
Aspergillus brasiliensis (formerly *A. niger*)	16404	10-100	5 days at 20-25 °C	Visible growth

Please refer to the actual batch related Certificate of Analysis.

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.

Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice.

Hawkey, P.H., McCormick, A. and Simpson, R.A. (1986). Selective and differential medium for the primary isolation of members of the *Proteae*. J. Clin. Microbiol. **23**: 600-603.

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.

PDA Technical Report No. 13 (2014 Revised): Fundamentals of an Environmental Monitoring Program.

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® prime Tryptic Soy Broth (TSB), Casein-Peptone Soymeal-Peptone (CASO) Broth	1.05459.0500	500 g
GranuCult® prime Tryptic Soy Broth (TSB), Casein-Peptone Soymeal-Peptone (CASO) Broth	1.05459.5000	5 kg
GranuCult® prime Tryptic Soy Broth (TSB), Casein-Peptone Soymeal-Peptone (CASO) Broth	1.05459.9025	25 kg
GranuCult® prime Tryptic Soy Agar acc. EP, USP, JP, ISO and FDA-BAM	1.05458.0500	500 g
GranuCult® prime Tryptic Soy Agar acc. EP, USP, JP, ISO and FDA-BAM	1.05458.5000	5 kg

MilliporeSigma