Technical Data Sheet

GranuCult® prime Tryptic Soy Broth (TSB) non-animal origin, irradiated

Ordering number: 1.00550.0500 / 1.00550.5000

Dehydrated culture medium with vegetable peptones as a non-animal origin alternative to Soybean Casein Digest Medium (SCDM), also referred to as Tryptic Soy Broth. The Broth is cold filterable and irradiated for the microbiological validation of aseptic filling processes (Aseptic Process Simulation (APS), also known as Media Fill).

The broth is suitable for APS according to the recommendations of the "FDA Aseptic Guide" and EU GMP Annex 1 in aseptic production lines. The exclusive use of raw materials of non-animal origin allows the elimination of a potential contamination risk with TSE/BSE.

The formulation of the basic medium (Vegetable Peptone Broth) is prepared according to the recommendations of the current European and United States Pharmacopoeia (Pharm Eur, 2.6.12. and USP, 61), but contains peptones of non animal origin instead of the recommended peptones. EP, USP, JP, FDA Aseptic Guide, EU GMP Annex 1, PIC/S Guidance and PDA TR 22 specify no media composition for aseptic process simulation.

Mode of Action

The microbiological performance of TSB non-animal origin is equivalent to the standard TSB.

The dehydrated culture medium is irradiated at a dose range of 48-90 kG. The intensity of irradiation guarantees that bacteria, spores, viruses and mycoplasma are destroyed. It provides a higher level of security regarding radiation-resistant microorganisms than other commercially available products. The absence of viable mycoplasma is verified using a validated qPCR method based on the recommendation of Pharm Eur 2.6.7 after elimination of free mycoplasma DNA.

Due to the rich nutrient base, this medium is also suitable for the cultivation of even fastidious microorganisms.

The medium is very suitable for the simulation of aseptic filling processes. The product is irradiated and triple-bagged allowing for safe introduction into controlled cleanroom areas. It is granulated which guarantees excellent solubility even in cold water. The previously aseptically prepared nutrient medium can be used for the simulation of the aseptic filling of liquids. As sterile filtration is the key element to achieve sterility autoclaving is not required. Cold filterability is achieved by extensive testing comprising raw materials, pre-production samples, in-process and end product control.

Typical Composition

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Peptone (non-animal origin)	20 g/L
D(+)-Glucose Monohydrate	2.5 g/L
NaCl	5.0 g/L
K_2HPO_4	2.5 g/L

Preparation

Dissolve 30 g in 1 L of sterile, demineralized water. Use according to the purpose required. The prepared 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 medium is used, e.g. follow directions given by FDA "Aseptic Guide", EU GMP Annex 1 or PIC/S PI007-6.

Storage and Shelf Life

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 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 3 days at 20-25 °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
Streptococcus pneumoniae	6301	10-100	18-24 h at 30-35 °C	Visible Growth
Bacillus spizizenii (formerly B. subtilis)	6633	10-100	18-24 h at 30-35 °C 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
Pseudomonas paraeruginosa (formerly P. aeruginosa)	9027	10-100	18-24 h at 30-35 °C	Visible Growth
Salmonella enterica subsp. enterica (formerly S. typhimurium)	14028	10-100	18-24 h at 30-35 °C	Visible Growth

Please refer to the actual batch related Certificate of Analysis.

Test	Incubation / Method	Results
Stability test	7 days at room temperature	Clear
Test for absence of microbial contamination	2 weeks at 20-25 °C	No growth, passes test
Test for absence of microbial contamination	2 weeks at 30-35 °C	No growth, passes test
Mycoplasma	qPCR	Negative

Literature

EU GMP Annex 1 (2022): Manufacture of Sterile Medicinal Products. EudraLex. The Rules Governing Medicinal Products in the European Union. Volume 4: EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinarian Use. Chapter 1: Pharmaceutical Quality System. European Commission, Brussels, Belgium.

European Directorate for the Quality of Medicines and Healthcare (2022): The European Pharmacopoeia. 11th Ed. Chapter 2.6.1 Sterility, Chapter 2.6.12 Microbiological examination of non-sterile products: Microbial enumeration tests, Chapter 2.6.13 Microbiological examination of non-sterile products: Test for specified products and Chapter 2.6.7. Mycoplasma. Strasbourg, France.

FDA Aseptic Guide (2004): Guidance for Industry. Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice. U.S. Food and Drug Administration – FDA Guidance Documents.

Japanese Ministry of Health, Labour and Welfare. (2021): The Japanese Pharmacopoeia. 18th 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 and Chapter 4.06 Sterility test. Japanese Ministry of Health, Labour and Welfare. Tokyo, Japan.

PDA Technical Report No. 22 (2011 Revised): Process Simulation for Aseptically Filled Products. Parenteral Drug Association, Bethesda, MD, USA.

PIC/S (2011): Recommendation on the Validation of Aseptic Processing (PI 007-6). Pharmaceutical Inspection Convention. Pharmaceutical Inspection Co-operation Scheme. Geneva, Switzerland.

United States Pharmacopeial Convention. (2022): The United States Pharmacopeia/National Formulation. Chapter ⟨61⟩ Microbiological examination of nonsterile products: Microbial enumeration tests, Chapter ⟨62⟩ Microbiological examination of nonsterile products: Test for specified micro-organisms and Chapter ⟨71⟩ Sterility tests. Rockville, Md., USA.

Ordering information

Product	Cat. No.	Pack size
GranuCult® Prime Tryptic Soy Broth (TSB) non-animal origin, irradiated	1.00550.0500	500 g
GranuCult® Prime Tryptic Soy Broth (TSB) non-animal origin, irradiated	1.00550.5000	5 kg

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