Technical Data Sheet

# GranuCult® prime Thioglycolate Broth non-animal origin, irradiated

## Ordering number: 1.08720.5000

A dehydrated culture medium with vegetable peptones as a non-animal-origin alternative to Thioglycolate Broth (FTM). The broth is cold filterable and irradiated.

The culture medium is suitable for aseptic process simulation (APS, also known as Media Fill), according to the recommendations of the FDA Aseptic Guide, EU GMP Annex 1, PIC/S Guidance, and PDA TR 22.

The culture medium is manufactured without the use of raw materials of animal origin, and the enzyme used for the peptone digestion is of non-animal origin. Based on this fact, the risk of BSE or similar infectious diseases is reduced to an utmost minimum, if not eliminated.

The formulation of the culture medium is based on the recommended specifications for the alternative Fluid Thioglycolate Medium without agar and resazurin sodium solution, as given by the harmonized methods of EP, USP, and JP for Sterility Tests. It contains peptones of non-animal origin instead of the recommended pancreatic digest of casein.

### Mode of Action

The microbiological performance of Thioglycolate Broth (non-animal origin, irradiated) is equivalent to that of Fluid Thioglycolate Medium as per EP, USP, and JP.

The culture medium is designed for the simulation of aseptic filling processes (APS). The product is irradiated and triple-bagged, allowing for safe introduction into controlled areas. It is granulated, which ensures excellent solubility even in cold water. The previously aseptically prepared nutrient medium can be used for the simulation of the aseptic filling of liquids, including the step of sterile filtration. Cold filterability is achieved through extensive testing comprising raw materials, pre-production samples, in-process controls, as well as controls of the final product.

The intensity of irradiation guarantees that bacteria, yeasts, molds (including their spores), viruses, and mycoplasma are destroyed, providing a high level of security with regard to radiation-resistant microorganisms.
The peptone from non-animal origin provides high nutrition by supplying organic nitrogen, amino acids, and longer-chained peptides. In this complex medium, the osmotic balance is maintained by sodium chloride, while dipotassium phosphate acts as a buffer.
Due to the rich nutrient base, this medium is also suitable for the cultivation of fastidious microorganisms.

### Typical Composition

EP, USP, JP, FDA Aseptic Guide, EU GMP Annex 1, PIC/S Guidance and PDA TR 22 specify no composition for culture media used in APS.

| GranuCult® prime<br>Thioglycolate Broth non-animal origin, irradiated | |
|---|---|
| Peptone non-animal origin | 15.0 g/l |
| Yeast Extract | 5.0 g/l |
| D(+)Glucose monohydrate | 5.5 g/l |
| NaCl | 2.5 g/l |
| L-Cystine | 0.5 g/l |
| Sodium Thioglycolate | 0.5 g/l |
| Final pH at 25 °C | 7.1 ± 0.2 |

## Preparation

Dissolve 30.0 g in 1 liter of purified and sterile water. As sterile filtration is the key element to achieve sterility, autoclaving is not required. The dehydrated medium is a granulate with a beige color. The prepared medium is clear and yellowish-brown. The pH value at 25 °C is in the range of 7.1 ± 0.2.

## Experimental Procedure and Evaluation

Depending on the purpose for which the medium is used, follow the directions provided by the FDA Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice, or EU GMP Annex 1: Manufacture of Sterile Medicinal Products.

## Storage

Store at +15 °C to +25 °C in a dry and tightly closed container. Do not use clumped or discolored medium. Protect from UV light (including sunlight). Transport is performed at ambient temperatures.

## Quality Control

| Control strains | Incubation | Inoculum | Expected results |
|---|---|---|---|
| *Bacillus spizizenii* (formerly *B. subtilis*) ATCC® 6633 [WDCM 00003] | ≤ 3 days at 30 – 35 °C, aerobic | ≤ 100 cfu | Growth (visible growth) |
| *Kocuria rhizophila* ATCC® 9341 | | ≤ 100 cfu | |
| *Pseudomonas aeruginosa* ATCC® 9027 [WDCM 00026] | | ≤ 100 cfu | |
| *Staphylococcus aureus* ATCC® 6538 [WDCM 00032] | | ≤ 100 cfu | |
| *Bacteroides vulgatus* ATCC® 8482 | ≤ 3 days at 30 – 35 °C, anaerobic | ≤ 100 cfu | Growth (visible growth) |
| *Clostridium sporogenes* ATCC® 19404 [WDCM 00008] | | ≤ 100 cfu | |
| *Clostridium sporogenes* ATCC® 11437 | | ≤ 100 cfu | |

Please refer to the actual batch related Certificate of Analysis.

The performance tests are in accordance with the harmonized methods of EP, USP and JP.

| Test | Incubation / Method | Expected results |
|---|---|---|
| Appearance filtered | 14 days at 35 °C | Clear, passes test |
| Test for absence of microbial contamination | 2 weeks at 20 – 25 °C | No growth, passes test |
| | 2 weeks at 30 – 35 °C | No growth, passes test |
| Absence of viable Mycoplasma | qPCR | Negative, passes test |

## 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 and Chapter 2.6.13 Microbiological examination of non-sterile products: Test for specified products. 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<br>Thioglycolate Broth non-animal, irradiated | 1.08720.5000 | 5 kg |

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