Technical Data Sheet

GranuCult® prime Vegetable Peptone Broth Halal irradiated

Ordering number: 1.02754.0500 / 1.02754.5000

A 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 (TSB). 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 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 vegetable origin. Based on this fact a BSE or similar infectious disease risk is reduced to an utmost minimum respectively does not exist.

The formulation of the Vegetable Peptone Broth halal irradiated is based on the recommended specifications given by the harmonized methods of EP, USP, JP for Sterility Test. It contains peptones of non-animal origin instead of the recommended peptones.

The Halal Certificate is issued by Halal Quality Control (HQC) according to Reference Halal Standards: JAKIM MS 1500:2019, MUI HAS 23000, OIC/SMIIC1:2019, GSO 2055-1.

Mode of Action

The microbiological performance of Vegetable Peptone Broth halal irradiated is equivalent to the Tryptic Soy Broth acc. EP, USP, JP.

The culture medium is very suitable for the simulation of aseptic filling processes. 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. Therefore, autoclaving is not required. Cold filterability is achieved by extensive testing comprising raw materials, pre-production samples, in-process and end product controls.

The dehydrated culture medium is irradiated with 48-90 kGy. The intensity of irradiation guarantees that bacteria, yeasts and moulds including their spores, viruses and mycoplasma are destroyed and provides a high level of security with regards to radiation-resistant microorganisms.

The absence of viable mycoplasma is determined based on the descriptions of the Pharm Eur. 2.6.7. using qPCR after previous elimination of free mycoplasma DNA

The peptone from non-animal origin 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 the dipotassium phosphate acts for buffering.

Due to the rich nutrient base, this medium is also suitable for the cultivation of even 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 Vegetable Peptone Broth for aseptic process simulation.

Typical composition	
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
Water	n/a
pH at 25 °C	7.3 ± 0.2

Preparation

Dissolve 30.0 g in 1 liter of purified and sterile water. The dehydrated medium is a granulate with beige color. The prepared medium is clear and yellowish-brown. The pH value at 25 °C is in the range of 7.3 ± 0.2.

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

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

Control Strains	ATCC #	Inoculum	Incubation	Expected Results
Staphylococcus aureus	6538 [WDCM 00032]	≤ 100 cfu	≤ 18 h at 30 – 35 °C, aerobic	Growth (visible growth)
Pseudomonas aeruginosa	9027 [WDCM 00026]			
Escherichia coli	8739 (WDCM 00012)			
Salmonella enterica subsp. enterica (formerly S. typhimurium)"	14028 (WDCM 00031)			
Bacillus spizizenii (formerly B. subtilis)"	6633 [WDCM 00003]	≤ 100 cfu	18 – 24 h at 30 – 35 °C, aerobic	Growth (visible growth)
Staphylococcus aureus	6538 [WDCM 00032]	≤ 100 cfu	3 days at 20 - 25 °C, aerobic	Growth (visible growth)
Bacillus spizizenii (formerly B. subtilis)"	6633 [WDCM 00003]			
Candida albicans	10231 [WDCM 00054]	≤ 100 cfu	up to 5 days at 20 - 25 °C, aerobic	Growth (visible growth)
Aspergillus brasiliensis	16404 [WDCM 00053]			

Please Reference medium for bacteria: Tryptic Soy Agar, already validated.
For *Candida albicans* and *Aspergillus brasiliensis*: Sabouraud 4% Dextrose Agar, already validated.

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	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 and 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

Ordering information

Product	Cat. No.	Pack size
GranuCult® prime Vegetable Peptone Broth Halal, irradiated	1.02754.0500	500 g
GranuCult® prime Vegetable Peptone Broth Halal, irradiated	1.02754.5000	5 kg

Find contact information for your country at: SigmaAldrich.com/offices

For Technical Service, please visit: SigmaAldrich.com/techservice

For more information, visit: SigmaAldrich.com/microbiology

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt
Germany

Lit. No. MK_DS13977EN Ver. 2.0
08/2024