Product :
TRYPTIC SOY BROTH IRRADIATED

Also known as
Irradiated TSB

Specification
General liquid medium, sterilized by gamma-radiation to suit *Media Fill Test*s in the pharmaceutical industry.

Formula * in g/L
Casein peptone..... 17,0
Soya peptone..... 3,0
Sodium chloride..... 5,0
Dipotassium phosphate.....2,5
Dextrose.....2,5

Final pH 7,3 ±0,2 at 25 ºC
* Adjusted and /or supplemented as required to meet performance criteria

Directions
For liquid filling tests: Suspend 30 g in 1 L of sterile distilled water and mix well to dissolve. Use for liquid fill validation procedures.
For solid filling tests: Use powder for dry-fill validation procedures. Ensure that the final concentration of the medium is 30 g of Irradiated TSB suspended in 1 L of sterile distilled water.

Description
The Irradiated Tryptone Soy Broth (Irradiated TSB) is the classical TSB culture medium sterilized by a gamma-irradiation process making it appropriate for validation of aseptic filling processes in the pharmaceutical industry (Media-Fill Test).
The sterility of the dehydrated culture medium is verified according to the methodology as described in the pharmacopoeia. It is subjected to exactly the same conditions as the pharmaceutical product, including filling and closing to ensure that there is no microbial contamination occurring during the process.
The gamma-irradiation treatment is carried out according to the Annex B of the ISO 11137 Standard, and warrants a 25 kGy absorption by the medium, which is enough to suppress any vegetative and/or spore from of microorganisms present in the powder without modification of the medium's performance. All batches of Irradiated TSB are checked for sterility and performance.

Technique
All the conditions and data for the validation of aseptic filling process can be consulted in the ISO Standard 13408-1 in the chapters devoted to the methods of preparation of sterile products in several Pharmacopoeias.

Quality control
Incubation temperature: 30-35°C **Incubation time:** 18-72h/ ≤ 5d (fungi)
Inoculum: Practical range 10-100 CFU. Min. 50 CFU (Productivity) according to Eur. Pharm. harm.

Microorganism	Growth	Remarks
Bacillus subtilis ATCC® 6633	Good	≤ 3 days
Staphylococcus aureus ATCC® 6538	Good	≤ 3 days
Escherichia coli ATCC® 8739	Good	-
Salmonella typhimurium ATCC® 14028	Good	-
Candida albicans ATCC® 10231	Good	≤ 5 days
Aspergillus brasiliensis ATCC® 16404	Good	≤ 5 days
Pseudomonas aeruginosa ATCC® 9027	Good	≤ 3 days

References

· EUROPEAN PHARMACOPOEIA 10.0 (2020) 10th ed. § 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. EDQM. Council of Europe. Strasbourg.
· ISO Standard 11137: 1995. Sterilization of health care products - Requirements for validation and routine control - Radiation Sterilization. (Annex B).
· ISO/TS 11133-1: 2009 Microbiology of food and animal feeding stuffs.- Guidelines on preparation and production of culture media. Part 1: General guidelines on quality assurance for the preparation of culture media in the laboratory.
· ISO/TS 11133-2: 2003 Corr. 2004 Microbiology of food and animal feeding stuffs.- Guidelines on preparation and production of culture media. Part 2: Practical guidelines on performance testing of culture media.
· ISO Standard 13408-1: 1998. Aseptic processing of health care products - Part 1: General requirements.
· US PHARMACOPOEIA 28 / NATIONAL FORMULARY 23 (2005) General Chapters § <71> Sterility Tests y § <1208> Sterilization and Sterility Assurance of Compendial Articles.

Storage

For laboratory use only. Keep tightly closed, away from bright light, in a cool dry place (+4 ºC to 30 ºC).