

# Tryptic Soy Broth (TSB) non-animal origin, irradiated

## Caso Broth non-animal origin, irradiated

Dehydrated culture media sterilised by irradiation for the microbiological validation of aseptic filling (Media Fill Test)

### General Information

The dehydrated culture medium is irradiated with 48-62 kGy gamma. The intensity of irradiation guarantees that Bacteria, spores, viruses and mycoplasma are destroyed. The test for sterility is carried out in compliance with European Pharmacopoeia and United States Pharmacopoeia (Ph. Eur. 2.6.1. Sterility).

### Mode of Action

The medium complies with the recommendations of USP XXVI (2003), EP (1999) and the Ph. Eur. (1999) German edition.

The microbiological performance of CASO Broth non-animal origin is equivalent to the common CASO Broth.

### Typical Composition (g/litre)

Peptone, non-animal origin 20.0; D(+)-glucose 2.5; sodium chloride 5.0; di-potassium hydrogen phosphate 2.5.

### Preparation

Suspend 30.0 g in 1 litre of sterile, demin. Water and use according to the purpose required.

pH: 7.3 ± 0.2 at 25 °C

The prepared medium is clear and yellowish-brown.

### Experimental Procedure and Evaluation

The medium is very suitable for the simulation of aseptic filling of sterile powder. The filled powder is readily soluble in sterile purified water and can be dissolved directly together with the filled units. The previously aseptically prepared nutrient medium can be used for the simulation of the aseptic filling of liquids. For the validation of the aseptic filling at least 3.000 units per run are expected to be filled. The contamination rate should be < 1/1000 at a probability of 95 %. (EU-GMP guidelines, Annex 1, ISO 13408-1). A growth control should be carried out for each run. The strains listed in the table below serve as growth controls, whereby bacteria should demonstrate good growth after 3 days of incubation at the (latest and yeasts and moulds after 5 days).

### Literature

Deutsches Arzneibuch, 10. Auflage; European Pharmacopoeia II; United States Pharmacopoeia XXVI; ISO 13408-1, 1998-08-00, Aseptische Herstellung von Produkten für die Gesundheitsfürsorge-Teil 1, Allgemeine Anforderungen.

### Ordering Information

Product	Ordering No.	Pack size
Tryptic Soy Broth (TSB) non-animal origin, irradiated	1.00550.5000	5 kg

### Quality control (inoculum about 10 – 100 microorganisms)

Test strains	Growth
<b>Incubation 24 h at 35 °C</b>	
Escherichia coli ATCC 8739	+
Staphylococcus aureus ATCC 6538	+
Streptococcus pneumoniae ATCC 6301	+
Bacillus subtilis ATCC 6633	+
Pseudomonas aeruginosa ATCC 9027	+
Salmonella typhimurium ATCC 14028	+
<b>Incubation 3 days at 20 - 25 °C</b>	
Staphylococcus aureus ATCC 6538	+
Staphylococcus aureus ATCC 25923	+
Staphylococcus aureus ATCC 12228	+
Bacillus subtilis ATCC 6633	+
<b>Incubation 5 day at 20 - 25 °C</b>	
Candida albicans ATCC 2091	+
Candida albicans ATCC 10231	+
Aspergillus niger ATCC 16404	+

Sterility test (2 weeks at 20-25 °C and 30-35 °C): no growth