

Tryptone – Soy Broth (TSB500)

In vitro diagnostic medical aid.

Only for professional use.

Sterile

Purpose: The product is designed for non-selective growth of bacteria and micromycetes – culture medium prescribed by PhEur for sterility tests.

Package contents: 500 ml solution in a bottle

Composition: casein peptone (17 g/l)
soy peptone (3 g/l)
glucose (2.5 g/l)
potassium hydrogen phosphate (2.5 g/l)
sodium chloride (5 g/l)
demineralized water

Storage: Store in a cool place at +2 to +8°C.

Usability: Use within 24 hours after opening the primary packaging.

Procedure: Aseptically divide the culture medium in the required volumes into the flasks of the respective volume.

1. Use to check the functionality of sterilizing devices.

Aseptically place a test strip containing spores of *Bacillus atropheus* CCM 4624 in a tube containing universal liquid medium (TSB). Cultivate at 37 °C ± 1 °C for 72 hours.

2. Use to control sterility and microbiological purity of pharmaceutical products.

Use to control sterility:

Inoculate a suitable amount of sample according to table no. 2.6.1-2 listed in the European Pharmacopoeia in Article 2.6.1 Sterility into the tryptone – soy broth so that the volume of the test sample does not exceed 10% of the medium volume. Incubate at 20-25 °C for 14 days.

Use as part of microbiological purity control:

To determine the total number of microorganisms according to PhEur 2.6.12, use tryptone – soy broth to dilute samples in a ratio of 1:10. To determine the specified microorganisms according to PhEur 2.6.13 after pre-diluting the sample in a ratio of 1:10, inoculate 10 ml of the sample into the tryptone – soy broth and incubate for 18-24 hours at 30-35 °C. Subsequently, inoculate the broth to the prescribed selective culture media.

Information for users: Do not use after the expiration date.

Dispose of used and unused products as hazardous waste in accordance with applicable regulations.

Instructions in case of a damaged packaging: In case of damage to the packaging, do not use and dispose of the product.

Quality control:

Type of inspection	Inoculated culture	Result
Positive check	<i>Bacillus subtilis</i> CCM1999 <i>Aspergillus brasiliensis</i> CCM8222 <i>Candida albicans</i> CCM8215	Growth in a form of turbidity
Negative check	<i>Uninoculated medium</i>	Without a change

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