Reference : 02-512 ***Scharlau Microbiology* - Technical data sheet**

Product :
NEUTRALIZING FLUID (Eur. Pharm.)

Specification

Liquid medium for neutralizing antimicrobials, according to the European Pharmacopoeia.

Formula * in g/L

Peptone..... 1,00
L-Histidine HCl..... 1,00
Lecithin..... 3,00
Monopotassium phosphate..... 3,60
Disodium phosphate..... 7,20
Sodium chloride..... 4,30

Final pH 7,0 ±0,2 at 25 ºC

* Adjusted and /or supplemented as required to meet performance criteria

Directions

Dissolve 20,1 g of powder in 1 L of distilled water containing 30 mL of Polysorbate 80 (Art. No. TW0080). Distribute into suitable containers and sterilize in the autoclave at 121ºC for 15 minutes. Cool to 50ºC and homogenize the solution.

Description

Neutralizing Fluid is formulated according to the European Pharmacopoeia specification for the microbiological examination of non-sterile products. Its composition is the same as the general diluting solution for biological assays with the addition of polysorbate and lecithin as non toxic neutralizing agents.
However, the European Pharmacopoeia allows the concentration of inactivator to be changed depending on the preservative being neutralised. of inactivators according to the European Pharmacopoeia, that must be added aseptically to the neutralizing fluid once sterilized and cooled to 50ºC or below.

Quality control

Incubation temperature: 35°C ±2,0 **Incubation time:** 24 h

Inoculum: 10-100 CFU. (Productivity) at 0, 45 minutes and 3 h. (20-25ºC)

Microorganism	Growth	Remarks
Staphylococcus aureus ATCC® 6538	Good	Recovery ±30% T0 in TSA
Pseudomonas aeruginosa ATCC® 9027	Good	Recovery ±30% T0 in TSA
Candida albicans ATCC® 10231	Good	Recovery ±30% T0 in SDA
Escherichia coli ATCC® 8739	Good	Recovery ±30% T0 in TSA
Salmonella typhimurium ATCC® 14028	Good	Recovery ±30% T0 in TSA
Bacillus subtilis ATCC® 6633	Good	Recovery ±30% T0 in TSA

References

· EUROPEAN PHARMACOPOEIA (2018) 9th ed. § 2.6.12. Microbiological examination of Non-sterile products.: Microbial Enumeration Test. Harmonised Method. EDQM. Council of Europe. Strasbourg.

· EUROPEAN PHARMACOPOEIA (2018) 9th ed. § 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. EDQM. Council of Europe. Strasbourg.

Storage

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