

TECHNICAL DATA SHEET

Article No. 9030

Fluid A (peptone wash and rinse solution) EP, USP, ready-to-use medium

SPECIFICATION

For use as rinsing and/or diluting fluid for membrane filtration methods according to USP and harmonized European Pharmacopoeia.

Colour: yellowish
pH: 7.1 ± 0.2 at 25 °C

COMPOSITION IN G/L

Peptic digest of animal tissue 1.00

PACKAGING DETAILS

9030-10x100ML

Content 100 ± 3 ml
Bottle size 125 ml
Packaging unit 10 bottles
1 box with 10 x 100 ml in 250-ml-bottles. Injectable cap: Plastic screw inner cap for use with syringe needles with a diameter ≤ 0.8 mm.

9030-10x300ML

Content 300 ± 5 ml
Bottle size 500 ml
Packaging unit 10 bottles
1 box with 10 x 300 ml in 500-ml-bottles. Injectable cap: Plastic screw inner cap for use with syringe needles with a diameter ≤ 0.8 mm.

9030-10x450ML

Content 450 ± 5 ml
Bottle size 500 ml
Packaging unit 10 bottles
1 box with 10 x 450 ml in 500-ml-bottles. Injectable cap: Plastic screw inner cap for use with syringe needles with a diameter ≤ 0.8 mm.



GUIDELINES

Description:

Diluent and non-selective pre-enrichment medium, that has the property of revitalization to samples by the presence of meat peptone in the formulation.

Technique:

Inoculate according to final purpose, samples and validated methods.

MICROBIOLOGICAL CONTROL

Prepare tubes - Inoculate: Practical range 100 ± 20 CFU. min. 50 CFU (productivity).

Subculture in appropriate culture media after T0 (inoculum), 45 min. - 1 h at 20-25 °C.

Analytical methodology according to ISO 11133:2014/A1:2018; A2:2020

Aerobiosis. Incubation at 35 ± 2 °C, reading after 18-24 hours.

Microorganism	Growth
<i>Bacillus subtilis</i> ATCC® 6633, WDCM 00003	Good. Recovery $\pm 30\%$ T0 (original enumeration)
<i>Escherichia coli</i> ATCC® 8739, WDCM 00012	Good. Recovery $\pm 30\%$ T0 (original enumeration)
<i>Staphylococcus aureus</i> ATCC® 6538, WDCM 00032	Good. Recovery $\pm 30\%$ T0 (original enumeration)
<i>Candida albicans</i> ATCC® 10231, WDCM 00054	Good. Recovery $\pm 30\%$ T0 (original enumeration)
<i>Aspergillus brasiliensis</i> ATCC® 16404, WDCM 00053	Good. Recovery $\pm 30\%$ T0 (original enumeration)

Sterility control:

Incubation 48 hours at 30-35 °C and 48 hours at 20-25 °C: NO GROWTH.

Check at 7 days after incubation in same conditions.

BIBLIOGRAPHY

- EUROPEAN PHARMACOPOEIA 6.0 (2006) 6th ed. § 2.6.2. Biological test. EDQM. Council of Europe. Strasbourg.
- EUROPEAN PHARMACOPOEIA 8.0 (2014) 8th ed. § 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. EDQM. Council of Europe. Strasbourg.
- USP 33 - NF 28 (2011) <62> Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. USP Corp. Inc. Rockville. MD. USA.
- USP 33 - NF 28 (2011) <71> Sterility Tests. Harmonised Method. USP Corp. Inc. Rockville. MD. USA.

STORAGE

8–25 °C

SHELF LIFE

12 months unopened from date of production

created: 05.08.2022

