

TECHNICAL DATA SHEET

Article No. 9032

Solution D (peptone/polysorbate 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:	Colourless
pH:	7.1 ± 0.2 at 25 °C

COMPOSITION IN G/L

Meat peptone	1.00
Polysorbate 80	1.00

PACKAGING DETAILS

<u>9032-10x100ML</u>			
Volume	100 ± 5	ml	
Bottle size	125	ml	
Packaging unit	10	bottles	
1 box with 10 x 100 ml in	125-ml-bottles. Injecta	able cap:	Plastic screw inner cap for use with syringe needles with
a diameter ≤ 0.8 mm.			



Th. Geyer GmbH & Co. KG Dornierstr. 4 – 6 D-71272 Renningen Tel: +497159 1637-0 Fax: +497159 1637-710 renningen@thgeyer.de www.thgeyer.de

BW-Bank (Swift/BIC SOLADEST600) IBAN DE85600501010002036302 Postbank Stuttgart (SwiftBIC PBNKDEFFXXX) IBAN DE3260010070000020708 Deutsche Bank (SwiftBIC DEUTDESSXXX) IBAN DE06600700700125518100 St.-Nr. 70093/40018 / USI-IdNr. DE147510304 Amtgericht Stuttgarf / IRA-Nr. 254140 Persönlich haftende Gesellschafterin: Geyer Beteiligungsgesellschaft mbH Amtgericht Stuttgarf / IRB-Nr. 252035 Geschäftsführer: Lutz-Alexander Geyer / Oliver-Alexander Geyer / André Meise / Ralf Streicher



9032-10x400ML			
Volume	400 ± 5	ml	
Bottle size	500	ml	
Packaging unit	10	bottles	
1 box with 10 x 400 ml in 500-ml-bottles. Injectable cap: Plastic screw inner cap for use with syringe needles with			
a diameter ≤ 0.8 mm.			

 9032-6x600ML

 Volume
 600 ± 5
 ml

 Bottle size
 1
 l

 Packaging unit
 6
 bottles

 1 box with 10 x 600 ml in 1-l-bottles. Injectable cap: Plastic screw inner cap for use with syringe needles with a diameter ≤ 0.8 mm.

<u>9032-6x850ML</u>		
Volume	850 ± 5	ml
Bottle size	1	I
Packaging unit	6	bottles
1 box with 10 x 850 ml in 1-l-bottles. Injectable cap: Plastic screw inner cap for use with syringe needles with a diameter \leq 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

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

Microorganism	Growth
Escherichia coli ATCC [®] 25922, WDCM 00013	Good. Recovery ±30% T0 (original enumeration)
Staphylococcus aureus ATCC® 6538, WDCM 00032	Good. Recovery ±30% T0 (original enumeration)
Bacillus subtilis ATCC [®] 6633, WDCM 00003	Good. Recovery ±30% T0 (original enumeration)



Th. Geyer CmbH & Co. KG Dornierstr. 4 – 6 D-71272 Renningen Tel.: +49 7159 1637-0 Fax: +49 7159 1637-710 renningen@thgeyer.de www.thgeyer.de

BW-Bank (Swift/BIC SOLADEST600) IBAN DE85600501010002036302 Postbank Stuttgart (SwiftBIC PBNKDEFFXXX) IBAN DE3260010070000020708 Deutsche Bank (SwiftBIC DEUTDESSXXX) IBAN DE06600700700125518100 St.-Nr. 70093/40018 / USI-IdNr. DE147510304 Amtsgericht Stuttgarf / HRA-Nr. 254140 Persönlich haftende Gesellschafterin: Geyer Beteiligungsgesellschaft mbH Amtsgericht Stuttgarf / HRB-Nr. 252035 Geschäftsführer. Lutz-Alexander Geyer / Oliver-Alexander Geyer / André Meise / Ralf Streicher



Candida albicans ATCC® 10231, WDCM 00054

Good. Recovery ±30% T0 (original enumeration)

Aspergillus brasiliensis ATCC® 16404, WDCM 00053

Good. Recovery ±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 manufacture

updated: 14.09.2022



Th. Geyer GmbH & Co. KG Domierstr. 4 – 6 D-71272 Renningen Tel.: +49 7159 1637-0 Fax: +49 7159 1637-70 Fax: +49 7159 1637-710 renningen@tbgeyer.de

BW-Bank (Swift/BIC SOLADEST600) IBAN DE85600501010002036302 Postbank Stuttgart (Swift/BIC PBNKDEFFXXX) IBAN DE3260010070000020708 Deutsche Bank (Swift/BIC DEUTDESSXXX) IBAN DE06600700700125518100 St.-Nr. 70093/40018 / USI-IdNr. DE147510304 Amtsgericht Stuttgart / HRA-Nr. 254140 Persönlich haftende Gesellschafterin: Geyer Beteiligungsgesellschaft mbH Amtsgericht Stuttgart / HRB-Nr. 252035 Geschäftsführer: Lutz-Alexander Geyer / Oliver-Alexander Geyer / André Meise / Ralf Streicher