

# TECHNICAL DATA SHEET

Article No. 9036

Fluid K, ready-to-use culture medium

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## SPECIFICATION

Ready-to-use medium, bottles, sterile. Diluent for the homogenization of samples for the microbiological examination according to the European Pharmacopoeial Harmonised Method.

Colour: Pale Yellow  
pH: 6.9 ± 0.2 at 25 °C

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## COMPOSITION IN G/ L

Meat Peptone	5.00
Beef extract	3.00
Polysorbate 80	10.00

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## PACKAGE DETAILS

### 9036-10x300ML

Bottle size	500 ml
Volume	300 ± 5 ml
Packaging unit	10 bottles

1 box with 10 x 300 ml in 500-ml-bottles. Injectable cap: Plastic screw inner cap.  
For the use of syringe needles with a diameter ≤ 0.8 mm.

### 9036-10x450ML

Bottle size	500 ml
Volume	450 ± 5 ml
Packaging unit	10 bottles

1 box with 10 x 450 ml in 500-ml-bottles. Injectable cap: Plastic screw inner cap.  
For the use of syringe needles with a diameter ≤ 0.8 mm.



## DESCRIPTION/ TECHNIQUE

### 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:

Use the medium according to intended purposes, samples and validated methods.

## MICROBIOLOGICAL CONTROL

Prepare tubes - Inoculate: Practical range 10-100 CFU (productivity) according to harmonized Eur. Pharmacopoeia

According to USP & European Pharmacopoeia  
Analytical methodology according to ISO 11133:2014/A1:2018; A2:2020

Aerobiosis. Incubation at  $32.5 \pm 2.5$  °C, reading after 24-48 h

Microorganism	Growth
<i>Bacillus subtilis</i> ATCC® 6633, WDCM 00003	Good
<i>Escherichia coli</i> ATCC® 8739, WDCM 00012	Good
<i>Staphylococcus aureus</i> ATCC® 6538, WDCM 00032	Good
<i>Candida albicans</i> ATCC® 10231, WDCM 00054	Good
<i>Ps. aeruginosa</i> ATCC® 9027, WDCM 00026	Good
<i>Salmonella typhimurium</i> ATCC® 14028, WDCM 00031	Good

### 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.

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## REFERENCES

- 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.

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## STORAGE

8 - 25 °C

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## SHELF LIFE

16 months unopened from date of manufacture

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