

BUFFERED PEPTONE WATER EP, USP

Dilution fluid for microbial examination, conforms to harmonized USP/EP requirements.

TYPICAL FORMULA	(g/l)
Pancreatic Digest of Casein	1.00
Sodium Chloride	4.30
Sodium Phosphate Monobasic Anhydrous	5.77
Potassium Phosphate Dibasic	3.56
Final pH 7.0 ± 0.2	

DESCRIPTION

BUFFERED PEPTONE WATER EP, USP is a dilution fluid used for microbial examination of non-sterile products, as recommended in the Harmonized Microbial Limit Tests sections in the Ph. EP and USP.

PRINCIPLE

Enzymatic digest of casein is a source of nitrogen, carbon, vitamins and minerals. Sodium chloride maintains the osmotic balance. Sodium phosphate and potassium phosphate are the buffering agents. The combination of phosphate buffer, sodium chloride and peptone increases the viability of sensitive micro-organisms by providing an isotonic environment. This is of particular importance when trying to recover cells that may be stressed or sensitive to osmotic pressure.

PREPARATION

Check the content of the bottle is homogeneous and clear; if it is the case repeatedly turn the bottle upside down. BUFFERED PEPTONE WATER EP, USP can be used as such or divided, under aseptic conditions, in lower aliquots.

TECHNIQUE

Bring BUFFERED PEPTONE WATER EP, USP to room temperature or, preferably at 36±1°C. Dilute the sample as required. Inoculated onto growth media specific for the organism in question. Incubate at specified temperature and incubation time.

INTERPRETATION OF RESULTS

Refer to specific literature.

STORAGE

10-25°C away from light, until the expiry date on the label or until signs of deterioration or contamination are evident.

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is designed for professional use and must be used by properly trained operators only.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to the national and local regulations in force.

REFERENCES

1. US Pharmacopoeia 30 (2008).
2. European Pharmacopoeia 6.1. 2.6.12 Microbiological Examination of Non-Sterile Products: Harmonised Method: Microbial Enumeration tests 2.6.13 Microbiological Examination of Non-Sterile Products: Test for Specified Micro-organisms. B. Harmonised Method (2008).
3. Japanese Pharmacopoeia. 15 th Edition (2006).



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PRODUCT SPECIFICATIONS

NAME

BUFFERED PEPTONE WATER EP, USP

PRESENTATION

Glass bottles containing liquid medium

STORAGE

10-25°C

PACKAGING

Ref.	Content	Packaging
400040	6 flip cap bottles x 100 ml	6 bottles in cardboard box
400140	6 flip cap bottles x 300 ml	6 bottles in cardboard box
400240	6 flip cap bottles x 1000 ml	6 bottles in cardboard box
400340	6 screw cap bottles x 100 ml	6 bottles in cardboard box
400440	6 screw cap bottles x 200 ml	6 bottles in cardboard box

pH OF THE MEDIUM

7.0 ± 0.2

USE

BUFFERED PEPTONE WATER EP, USP is a dilution fluid used for microbial examination of non-sterile products, as recommended in the Harmonised Microbial Limit Tests sections in the Ph. EP and USP

TECHNIQUE

Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM

Colourless liquid, clear without precipitates

SHELF LIFE

2 years

QUALITY CONTROL

- Control of general characteristics, label and print
- Sterility control
7 days at 22 ± 1°C, in aerobiosis
7 days at 36 ± 1°C, in aerobiosis
- Microbiological control
The diluent bottles were held at room temperature. At "0" time, 2 hours, and 4 hours, 100 microliters from each bottle was inoculated onto growth media specific for each test strain. The cultures were tested at Harmonized USP/EP/JP specified temperatures and incubation times.










Microorganism

Escherichia coli ATCC® 25922
Salmonella typhimurium ATCC® 14028
Pseudomonas aeruginosa ATCC® 27853
Aspergillus niger ATCC® 16404
Candida albicans ATCC® 10231

Expected results

No marked increase or decrease in original CFU count
No marked increase or decrease in original CFU count
No marked increase or decrease in original CFU count
No marked increase or decrease in original CFU count
No marked increase or decrease in original CFU count

TABLE OF SYMBOLS

 Batch code	 Do not reuse	 Manufacturer	 Use by	 Fragile, handle with care
 Catalogue number	 Temperature limitation	 Contains sufficient for <n> tests	 Caution, see instructions for use	



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