Instructions for Use

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Dehydrated culture medium

1 - INTENDED USE

Monopotassium phosphate

Biolife

Buffered Peptone Water (Meat) is used as non-selective pre-enrichment medium or as a diluent in several microbiological procedures.

1.5 g

2 - COMPOSITION - TYPICAL FORMULA *	
(AFTER RECONSTITUTION WITH 1 L OF WATER)	
Enzymatic digest of animal tissue	10.0 g
Sodium chloride	5.0 g
Disodium hydrogen phosphate anhydrous	3.5 g ^

*The formula may be adjusted and/or supplemented to meet the required performances criteria.

^ equivalent to disodium hydrogen phosphate dodecahydrate 9 g/L

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

The ISO Standards in which Buffered Peptone Water is mentioned, specify the generic term 'Peptone' in the medium formulation and cite the enzymatic digest of casein as an example.¹⁻⁵ According to ISO 11133⁶, annex A, the term "peptone" is used to identify enzymatic digests of different biological materials (animal tissue, casein, soy, heart, gelatine, animal and plant tissue).

European Pharmacopoeia, recommending the use of Buffered Peptone Medium, indicates a material with the generic term "Peptone" as the ingredient of animal origin to be included in the formula without further specifying the origin of the animal tissue.⁷

Buffered Peptone Water (Meat) is manufactured with a selected enzymatic digest of animal tissue (meat), very rich in nutrients and with a buffer system that allows optimal recovery of microorganisms even when present in the sample in a very low number or sub-lethally injured.

Buffered Peptone Water (Meat) can be used as a non-selective pre-enrichment medium or as a diluent in several in procedures such as • detection of *Salmonella* according to ISO 6579¹ in samples of the food chain and according to EP⁷ in in herbal medicinal products for

- oral use and extracts used for their preparation
- detection of *Cronobacter* according to ISO 22964;²
- detection of *Enterobacteriaceae* according to ISO 22504,
 detection of *Enterobacteriaceae* according to ISO 21528;³
- enumeration of Listeria monocytogenes and of Listeria spp. according to ISO 11290-2;⁴
- preparation of the sample according to ISO 6887-1.⁵

The enzymatic digest of animal tissue provides carbon, nitrogen, vitamins and minerals for microbial growth, sodium chloride maintains the osmotic balance, while phosphates buffer the medium at pH 7.0.

4 - DIRECTIONS FOR DEHYDRATED MEDIUM PREPARATION

Suspend 20 g in 1000 mL of cold purified water. Mix thoroughly and warm gently to completely dissolve the powder, if necessary. Distribute into flasks or tubes of suitable capacity and sterilise in the autoclave at 121°C for 15 minutes.

5 - PHYSICAL CHARACTERISTICS

Dehydrated medium appearancebeige, fine, homogeneous, free-flowing powderPrepared medium appearanceyellow, limpidFinal pH at 20-25 °C7.0 ± 0.2

6 - MATERIALS PROVIDED - PACKAGING

Product	Туре	REF	Pack
Buffered Peptone Water (Meat)	Dehydrated medium		500 g (25 L)
		401278B4	5 kg (250 L)

7 - MATERIALS REQUIRED BUT NOT PROVIDED

Autoclave, sterile loops and pipettes, incubator and laboratory equipment as required, Erlenmeyer flasks, tubes, bottles, ancillary culture media and reagents.

8 – SPECIMENS

Food samples, herbal medicinal products and extracts used for their preparation. Refer to EP and Iso Standards for the collection, transport, storage of samples and operate in accordance with good laboratory practice.¹⁻⁷

9 - TEST PROCEDURE

For details of sample preparation and enrichment, refer to the Standards cited according to the intended use.^{1-5,7} Pre-enrichment for *Salmonella* detection: in general, 225 mL of Buffered Peptone Water are inoculated with 25 g of the test portion, then incubated between 34° C and 38° C for $18 \text{ h} \pm 2 \text{ h}$.

10 - READING AND INTERPRETATION

Microbial growth in Buffered Peptone Water (Meat) is evidenced by the development of turbidity in the broth.

11 - USER QUALITY CONTROL

All manufactured lots of the product are released for sale after the Quality Control has been performed to check the compliance with the specifications. However, the end user can perform its own Quality Control in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory. The choice of strains depends on the intended use. Consult the cited references.¹⁻⁷





12 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of dehydrated Buffered Peptone Water (Meat) (Test Batch: TB), is tested for productivity by comparing the results with a previously approved Reference Batch (RB).

Productivity is tested by dilution to extinction method, by inoculating 1 mL of appropriate decimal dilutions of organisms in test tubes and incubating at 35-37° for 18-24 hours and recording the highest dilution showing growth in Reference Batch (Gr_{RB}) and in Test Batch (Gr_{TB}). Productivity is tested with the following strains: *E.coli* ATCC 8739, S.Enteritidis ATCC 13076. The productivity index Gr_{RB} - Gr_{TB} for each test strain shall be \leq 1. Productivity is also tested with a growth curve of S.Typhimurium ATCC 14028, with subculture and enumeration onto Tryptic Soy Agar plates after 4, 8, 24 hours of incubation.

Moreover, Buffered Peptone Water is evaluated for test strains survival after 1 hour at 20°C into the device with subculture and enumeration in Tryptic Soy Agar. The ratio A/C (CFU obtained after 1 hour of incubation of the inoculated medium/CFU obtained immediately after the inoculation of the medium) shall be between 0.7 and 1,3 for the following strains: *E.coli* ATCC 8739, *L.monocytogenes* ATCC 13932, *S.aureus* ATCC 25923.

13 – LIMITATIONS OF THE METHOD

- Buffered Peptone Water (Meat) is a general-purpose medium without selective properties. Suitable selective liquid and solid media must be inoculated with the growth obtained in Buffered Peptone Water (Meat).
- The test sample may increase the turbidity of the medium although bacterial growth is not present. Subculture to appropriate media is necessary to verify growth of organisms.

14 - PRECAUTIONS AND WARNINGS

- This product is for microbiological control and for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- Dehydrated media must be handled with suitable protection. Before use, consult the Safety Data Sheet.
- This culture medium contains raw materials of animal origin. The ante and post mortem controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that the product doesn't contain any transmissible pathogen. Therefore, it is recommended that the culture medium be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- · Apply Good Manufacturing Practice in the production process of prepared media.
- All laboratory specimens should be considered infectious.
- · The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Sterilize all biohazard waste before disposal. Dispose the unused medium and the sterilized plates inoculated with samples or microbial strains in accordance with current local legislation.
- Do not use the culture medium as active ingredient for pharmaceutical preparations or as production material intended for human and animal consumption.
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website www.biolifeitaliana.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the
 proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be
 observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products
 intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the
 suitability of our product for the intended purpose.

15 - STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store at +10°C /+30°C away from direct light in a dry place. If properly stored, it may be used up to the expiration date. Do not use beyond this date. Avoid opening the bottle in humid places. After use, the container must be tightly closed. Discard the product if the container and/or the cap are damaged, or if the container is not well closed, or in case of evident deterioration of the powder (colour changes, hardening, large lumps).

The user is responsible for the manufacturing and quality control processes of prepared media and the validation of their shelf life, according to the type (tubes/flasks) and the applied storage conditions (temperature and packaging). According to ISO 6579-1¹ autoclaved Buffered Peptone Water may be stored in closed containers at 2-8 °C for up to six months.

16 - REFERENCES

- 1. ISO 6579-1:2017/AMD 1:2020 Microbiology of the food chain Horizontal method for the detection, enumeration and serotyping of Salmonella Part 1: Detection of Salmonella spp. Amendment 1: Broader range of incubation temperatures, amendment to the status of Annex D, and correction of the
- ISO 22964:2017 Microbiology of the food chain Horizontal method for the detection of Cronobacter spp.
 ISO 21528-1:2017 Microbiology of the food chain Horizontal method for the detection and enumeration of Enterobacteriaceae -Part 1: Detection of
- Enterobacteriaceae ISO 11290-2:2017 Microbiology of the food chain - Horizontal method for the detection and enumeration of Listeria monocytogenes and of Listeria spp. -
- Part 2: Enumeration method
 ISO 6887-1:2017 Microbiology of the food chain Preparation of test samples, initial suspension and decimal dilutions for microbiological examination Part 1: General rules for the preparation of the initial suspension and decimal dilutions
- 6. ISO 11133:2014 Microbiology of food, animal feed and water Preparation, production, storage and performance testing of culture media
- 7. European Pharmacopoeia 11th Edition, 2022, Vol. 1; 2.6.31 Microbiological Examination of herbal medicinal products for oral use and extracts: 01/2014:20631.





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TABLE OF APPLICABLE SYMBOLS

REF or REF Catalogue number	LOT Batch code	Manufacturer	Store in a dry place	Use by
Temperature limitation	Contents sufficient for <n> tests</n>	Consult Instructions for Use	Keep away from direct light	

REVISION HISTORY					
Version	Description of changes	Date			
Revision 2	Updated layout and content	2022/11			
Note: minor typographical, grammatical, and formatting changes are not included in the revision history.					

