IFU

Instructions for Use

BUFFERED NACL PEPTONE EP, USP

Cat. no. U255	Buffered NaCl Peptone EP, USP, 180ml Wide Mouth Jar, 90ml	12 jars/box
Cat. no. U301	Buffered NaCl Peptone EP, USP, 500ml Polycarbonate Bottle, 500ml	10 bottles/box
Cat. no. U287	Buffered NaCl Peptone with Tween® 80 EP, USP, 250ml Polycarbonate Bottle, 200ml	12 jars/box

INTENDED USE

Hardy Diagnostics Buffered NaCl Peptone EP is an isotonic agent recommended for use as a diluent in performing microbial examination of nonsterile products. The solution is used in the food, water and wastewater, pharmaceutical and cosmetic industries for microbial limits testing and enumeration procedures. Buffered NaCl Peptone EP is also recommended by the European Pharmacopoeia (EP) for the microbial examination of nonsterile products and meets the harmonization requirements of the U.S. Pharmacopeia (USP), EP and Japanese Pharmacopoeia (JP).[6,10-13,16]

This product is not intended to be used for the diagnosis of human disease.

SUMMARY

Buffered NaCl Peptone Water is a rinsing solution and pre-enrichment medium recommended as a diluent for the homogenization of samples for enumeration and microbial limits testing. It is used in the preparation of samples to dilute water-soluble products and non-fatty water insoluble products, and to promote the recovery of sub-lethally damaged *Salmonella* spp. The pre-enrichment medium is buffered, free of inhibitory agents and provides conditions for the resuscitation of cells that may have been injured by various processes of preservation.[15] Edel and Kampelmacher noted that sub-lethal injury to *Salmonella* may occur due to food preservation techniques such as heat, desiccation, high osmotic pressure, preservatives, or changes in pH.[7] Processes that result in pH changes are particularly important for testing items such as vegetable specimens, which have a low buffering capacity.

The composition of Buffered NaCl Peptone EP meets the harmonized U.S. Pharmacopeia (USP), European Pharmacopoeia (EP), Japanese Pharmacopoeia (JP), as well as the Indian Pharmacopoeia (IP), standards for use as a diluent in performing microbial examination of nonsterile products.[6,8-13,16]

Hardy Diagnostics Buffered NaCl Peptone EP contains peptone as a source of carbon, nitrogen, vitamins and minerals. Sodium chloride helps to maintain osmotic balance and the phosphate buffer system prevents bacterial cell damage due to changes in pH.

For Cat. no. U287, Tween® 80 is added to the formulation to neutralize disinfectant residues and aid in the suspension of substances. Neutralization of these residues reduces their inhibitory effect which would ultimately result in lowering of microbial count. Phenolic disinfectants and hexachlorophene are neutralized by Tween® 80.

FORMULA

Ingredients per liter of deionized water:*

Buffered NaCl Peptone EP (Cat. no. U255, U301)	
Disodium Phosphate	7.2gm
Sodium Chloride	4.3gm
Monopotassium Phosphate	3.6gm
Peptone	1.0gm

In additon, Buffered NaCl Peptone with Tween® 80 EP (Cat. no. U287) contains:

Tween® 80	5.0gm

Final pH 7.0 +/- 0.2 at 25ºC.

* Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-30ºC. away from direct light. Media should not be used if there are any signs of deterioration, discoloration, contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual universal blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for laboratory use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

PROCEDURE

Method of Use: For use as a dilution buffer, rinsing solution and homogenization pre-enrichment medium for the preparation of microbial suspensions. Consult listed references or the appropriate regulatory guidelines for more specific information on the correct procedure for use.[1-3,5,6,8-13]

INTERPRETATION OF RESULTS

Observe colonies subcultured to an appropriate selective and/or differential medium for typical colonial morphology.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification of bacteria and/or fungi.

Do not suspend cultures containing bacteria in dilution buffer for more than 30 minutes at room temp as cell death or multiplication may occur.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, swabs, applicator sticks, other culture media, incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Buffered NaCl Peptone EP (Cat. no. U255, U301)					
Escherichia coli ATCC® 8739	J	48 hrs	30-35°C	Aerobic	Growth
Staphylococcus aureus ATCC® 6538	J	48 hrs	30-35°C	Aerobic	Growth
Buffered NaCl Peptone with Tween® 80 EP (Cat. no. U287)					
Staphylococcus aureus ATCC® 6538	J	24 hrs	30-35°C	Aerobic	Growth
Pseudomonas aeruginosa ATCC® 9027	J	24 hrs	30-35°C	Aerobic	Growth
Bacillus subtilis ATCC® 6633	J	24 hrs	30-35°C	Aerobic	Growth
Candida albicans ATCC® 10231	J	24 hrs	30-35°C	Aerobic	Growth
Aspergillus brasiliensis ATCC® 16404	J	24 hrs	30-35°C	Aerobic	Growth

* Refer to the document "Inoculation Procedures for Media QC" for more information.

USER QUALITY CONTROL

End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificate of analysis (CofA) available from Hardy Diagnostics Certificate of Analysis website. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

PHYSICAL APPEARANCE

Hardy Diagnostics Buffered NaCl Peptone EP should appear clear and colorless.

Hardy Diagnostics Buffered NaCl Peptone with Tween® 80 EP should appear clear to slightly hazy, with no precipitate or debris.

REFERENCES

1. American Public Health Association. *Standard Methods for the Examination of Dairy Products,* APHA, Washington, D.C.

2. APHA Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods,* APHA, Washington, D.C.

3. American Public Health Association. *Standard Methods for the Examination of Water and Wastewater,* APHA, Washington, D.C.

4. Anderson, N.L., et al. 2005. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory,* Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.

5. Association of Official Analytical Chemists. *Official Methods of Analysis*^{sm}AOAC, Washington, D.C.

6. Clontz, Lucia. 2009. Microbial Limit and Bioburden Tests: Validation Approaches and Global Requirements. RCR Press. Taylow and Francis Group. Boca Raton, FL.

7. Edel and Kampelmacher. 1973. *Bull. W.H.O.*; 48:167.

8. European Pharmacopoeia. 2008. European Directorate for the Quality of Medicine.

9. Indian Pharmacopoeia. 1997. Ministry of Health and Family Welfare. Govt. of India. Vol. 2.

10. Japanese Pharmacopoeia. 2001. The Ministry of Health, Labour and Welfare. Fourteenth Edition.

11. The Official Compendia of Standards. *USP-NF*. United States Pharmacopeial Convention, Rockville, MD.

12. The Official Compendia of Standards. USP General Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

13. The Official Compendia of Standards. USP General Chapter <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

14.*Quality Assurance for Commercially Prepared Microbiological Culture Media,* M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

15. Sadovski. 1977. *J. Food Technol.*; 12:85.

16. Sutton, Scott. 2006. The Harmonization of the Microbial Limits Test - Absence of Specified Organisms. The

Microbiology Network. www.microbiol.org/white.papers/WP.USP.62.htm.

17. The Official Compendia of Standards. USP General Chapter <60> Microbiological Examination of Nonsterile Products - Tests for Burkholderia cepacia Complex. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD

ATCC is a registered trademark of the American Type Culture Collection.

IFU-10094[B]

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The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

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