IFU

Instructions for Use

DNP BUFFER (NEUTRALIZING FLUID, EP)

Cat. no. U377	DNP Buffer, 8oz Boston Round Glass Bottle, 200ml	12 bottles/box

INTENDED USE

Hardy Diagnostics DNP Buffer (also known as Neutralizing Fluid, EP or Diluant Pharmacopee + Neutralisants) is recommended for neutralizing the activity of antimicrobial agents according to the European Pharmacopoeia (Ph. Eur.).

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

SUMMARY

Neutralizing buffers or fluids are used for microbial limits or sterility testing to neutralize the effects of antimicrobial agents present in medical devices, pharmaceutical products, or raw materials. Without the use of neutralizers, it may be difficult to fully assess the microbial load or sterility of such materials due to the presences of potential inhibitory ingredients or preservative in the sample.

DNP Buffer contains a small amount of peptone and histidine (an amino acid), which provide carbon, nitrogen, vitamins, and other essential nutrients to support cell metabolism. Sodium chloride helps cells maintain osmotic equilibrium, and phosphates act as buffering agents to maintain pH. Lecithin and Tween® (polysorbate) 80 are added to neutralize bactericidal or bacteriostatic agents that may be present in the sample. DNP Buffer is formulated in accordance with the formulation recommended by the European Pharmacopoeia (Ph. Eur.).(1)

FORMULA

Ingredients per liter of deionized water:*

Tween® 80	30.0g
Disodium Hydrogen Phosphate Dihydrate	7.2g
Sodium Chloride	4.3g
Potassium Dihydrogen Phosphate	3.6g
Lecithin	3.0g
Peptone	1.0g
Histidine Hydrochloride	1.0g

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 away from direct light 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

Sample Collection: Consult reference methods for information on sample collection or preparation.[1-3]

Method of Use: Allow medium to warm to room temperature prior to inoculation. Consult references for information concerning inoculation and subculture procedures.[1-3]

INTERPRETATION OF RESULTS

Consult listed references for appropriate interpretation of results.[1-3]

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.

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, 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	
Staphylococcus aureus ATCC® 6538	J	24hr	30-35°C	Aerobic	Growth
Pseudomonas aeruginosa ATCC® 9027	J	24hr	30-35°C	Aerobic	Growth
Bacillus subtilis ATCC® 6633	J	24hr	30-35°C	Aerobic	Growth
Candida albicans ATCC® 10231	J	24hr	20-25°C	Aerobic	Growth
Aspergillus brasiliensis ATCC® 16404	J	24hr	20-25°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

DNP Buffer should appear opalescent and light amber in color.

REFERENCES

1. *European Pharmacopoeia* (Ph. Eur.). 10th edition. EDQM Council of Europe. Strasbourg France.

2. *United States Pharmacopoeia and National Formulary* (USP-NF). Rockville, MD: United States Pharmacopeial Convention.

3. Association of Official Analytical Chemists. *Official Methods of Analysis*, AOAC, Washington, D.C.

ATCC is a registered trademark of the American Type Culture Collection.
Tween is a registered trademark of ICI Americas, Inc.

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Ordering Information

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

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