REF 42 623

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Buffered Peptone Solution with Neutralizers (DNP-F)

For microbiological control only

Neutralizing solution for non-sterile pharmaceutical products

SUMMARY AND EXPLANATION

The Buffered Peptone Solution pH 7.0 with Neutralizers (DNP) is a neutralizing solution recommended by the European Pharmacopoeia (1). It is used for the preparation of samples which have an antimicrobial effect or which are not soluble in water.
Its composition is described in the European Pharmacopoeia.

PRINCIPLE

The use of a low concentration of peptones is recommended by the Pharmacopoeia.
The presence of neutralizers (polysorbate 80, lecithin and histidine hydrochloride) enables phenolic compounds to be inactivated.

CONTENT OF THE KIT

	Ready-to-use medium
REF 42 623	6 x 90 ml bottles

COMPOSITION

Theoretical formula

These media can be adjusted and/or supplemented according to the performance criteria required:

Meat or casein peptone (bovine or porcine)	1 g
Polysorbate 80	30 g
Egg lecithin	3 g
Histidine hydrochloride	1 g
Sodium chloride	4.3 g
Potassium dihydrogen phosphate	3.6 g
Disodium hydrogenphosphate dihydrate	7.2 g
Purified water	1 l

pH 7.0

MATERIAL REQUIRED BUT NOT PROVIDED

- Bacteriology incubator.

WARNINGS AND PRECAUTIONS

- **For microbiological control only.**
- **For professional use only.**
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- All specimens, microbial cultures and inoculated products should be considered infectious and handled appropriately. Aseptic technique and usual precautions for handling the bacterial group studied should be observed throughout this procedure. Refer to "NCCLS M29-A, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue; Approved Guideline - Current Revision". For additional information on handling precautions, refer to "Biosafety in Microbiological and Biomedical Laboratories – CDC/NIH – Latest edition", or the current regulations in the country of use.
- The diluents should not be used as manufacturing material or components.
- Do not use reagents past the expiration date.
- Do not use bottles which show signs of contamination.
- A slight deposit, that can easily be resuspended by shaking, may be observed at the bottom of the bottle. This will not alter the performance of the solution.
- The medium should be used according to the procedure indicated in this package insert. Any change or modification in the procedure may affect the results.

STORAGE CONDITIONS

- **Store the bottles in their box at 2°C-25°C until the expiration date.**

SPECIMENS

Test samples should be collected from raw materials or non sterile pharmaceutical preparations.
Follow the recommendations of the pharmacopoeia to establish a sampling plan.

INSTRUCTIONS FOR USE

1. **Allow the bottles to come to room temperature.**
2. According to the European Pharmacopoeia, 10 ml or 10 g of sample are generally suspended and then homogenized in 90 ml of DNP.
3. Using this suspension, count the number of total viable aerobic organisms (mesophilic bacteria and fungal flora) or test for specific micro-organisms with media recommended by the Pharmacopoeia.

Note : The procedure may vary depending on the protocol used in the laboratory.

READING

Refer to the package inserts of the culture media used.

QUALITY CONTROL

The DNP was designed and developed to meet the strictest quality requirements.
The quality control results of strains tested batch by batch are given on the quality control certificate which is available on request.

LIMITATIONS OF THE METHOD

- Given the wide variety of specimens tested, it is the responsibility of the user to validate this solution in its specific application.
- After homogenization of the sample, the DNP and the test sample should not remain in contact for more than 30 minutes if the presence of anaerobic organisms is suspected.
- Small crystals may appear at the bottom of the bottles during storage, but they do not affect the performance of the medium.
- The presence of neutralizers may slow down the growth of certain microorganisms.

WASTE DISPOSAL

Dispose of used or unused reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

1. European Pharmacopoeia 5.0

INDEX OF SYMBOLS

Symbol	Meaning
	Catalogue number
	Manufacturer
	Temperature limitation
	Use by
	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests

WARRANTY

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