PHOSPHATE BUFFER (BUTTERFIELD’S BUFFER)

INTENDED USE
Remel Phosphate Buffer (Butterfield’s Buffer) is a liquid medium recommended for use in qualitative procedures as a diluent in microbial limit testing of pharmaceutical products and in food testing.

SUMMARY AND EXPLANATION
Phosphate Buffer (pH 7.2) was developed to provide a standardized medium for the preparation of sample dilutions. It eliminates the variations in pH associated with the use of distilled water. This buffer is recommended for use in the United States Pharmacopeia (USP) for microbial limit testing of pharmaceutical products.¹ The formulation is prepared according to current USP guidelines, which includes adjustment of the pH to 7.2 ± 0.1 prior to sterilization. It is also used in food testing as recommended by the American Public Health Association (APHA) and the Association of Official Analytical Chemists (AOAC).²⁻⁴ This buffer is also known as Butterfield’s Phosphate Buffered Dilution Water and Butterfield’s Phosphate Diluent.

PRINCIPLE
Potassium dihydrogen phosphate provides buffering action.

REAGENTS (CLASSICAL FORMULA)*
Potassium Dihydrogen Phosphate Stock Solution:
Monobasic Potassium Phosphate................................... 34.0 g Sodium Hydroxide, 1N.......................................175.0 ml
Demineralized Water.....................................................825.0 ml

Phosphate Buffer:
Potassium Dihydrogen Phosphate Stock Solution......... 1.25 ml Demineralized Water............................................. ......1000.0 ml

*Adjusted as required to meet performance standards.

PRECAUTIONS
This product is For Laboratory Use only. It is not intended for use in the diagnosis of disease or other conditions.

PROCEDURE
1. Consult appropriate references for the recommended procedure for sample inoculation and cultivation.

QUALITY CONTROL
All lot numbers of Phosphate (Butterfield’s) Buffer have been tested for microbial content and aesthetic value only, and have been found to be acceptable. To ensure efficacy of the product, functional testing should be performed by the user in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, sample results should not be reported.

BIBLIOGRAPHY

Refer to the front of Remel Technical Manual of Microbiological Media for General Information regarding precautions, product storage and deterioration, sample collection, storage and transportation, materials required, quality control, and limitations.

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