

TECHNICAL SHEET

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| BR003 | Diluting Fluid, A (PEP 0.1%) | |
| Formula | | |
| Ingredients: | gms/lit | |
| Peptic digest of animal tissue 1.000 | | |
| Final pH (at 25°C): 7.1 ± 0.2 | | |
| Directions: | | |
| Diluting fluid is used as the diluting or rinsing solution for membrane filter techniques in pharmaceutical products. Measured portions of Diluting fluid A should be used to rinse the membrane after filtration. Inoculate this rinse with 50-100 cfu of test organisms. Simultaneously run a positive control of the same medium. Incubate both the set of mediums at the specified time and temperature. Compare the growth obtained for the rinse with that obtained in the positive control after incubation. | | |
| Principle: | | |
| Diluting Fluid, A is recommended as rinsing fluid for membrane filter method used in validation tests for bacteriostasis and fungistasis activity of pharmaceutical articles before carrying out sterility test procedures as per USP. After filtering the specified quantity of the test specimen, the membrane is rinsed with measured portions of rinsing or diluting fluid. This rinse is inoculated with known number of test bacteria and fungi as specified in pharmacopoeia. The resultant growth is compared with positive control to determine presence of fungistasis or bacteriostasis activity in test specimen. | | |
| (I) QC Tests | | |
| pH: | 7.1 ± 0.2 | |
| Color: | Light yellow coloured medium | |
| Appearance: | Sterile clear Diluting Fluid A in bottle. | |
| (II) Sterility test | Passes release criteria | |
| (III) Q.C. Test Microbiological | | |
| Cultural characteristics observed after incubation at 35-37°C for 18-24 hours. | | |
| MICROORGANISM (ATCC) | GROWTH | |
| Escherichia coli 25922 | Good | |
| Candida albicans 10231 | Good | |
| Staphylococcus aureus 25923 | Good | |
| Staphylococcus aureus 6538 | Good | |

Refer disclaimer Overleaf

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| Precautions : | 1. In Vitro diagnostic use only. |
| | 2. Read the label before opening the container |
| Limitations : | 1. Since the nutritional requirements of organisms vary, some strains may be encountered that fail to grow or grow poorly on this medium. |
| Use: | Diluent in testing of pharmaceuticals in accordance with USP. Recommended for injectables for use in sterile rooms. |
| Storage: | Store between 2-8°C. Use before expiry date on the label. |
| Packing: | Sterile clear 100ml Diluting Fluid A in 5 glass bottles. |

Disclaimer:

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related BIOMARKLABORATORIES publications.

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