

TECHNICAL SHEET

B1168	DILUTING FLUID K				
Formula					
Ingredients :					
		gms/lit.			
Peptic digest of animal tissue	5.00				
Meat extract B#	3.00				
Polysorbate 80	10.00				
# Equivalent to Beef extract					
Final pH (at 25°C): 6.9± 0.2					
Directions :					
Suspend 18.0 grams in 1000 ml distilled water. Heat if necessary to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Dispense as desired.					
Principle :					
Diluting Fluid K 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.					
QC Tests – (I)Dehydrated Medium					
	Colour :				Cream to yellow
	Appearance :				Homogeneous Free Flowing powder
(II)Rehydrated medium					
	pH (post autoclaving/heating) :				6.9 ± 0.2
	Colour (post autoclaving/heating) :				Light yellow
	Clarity (post autoclaving/heating) :				Clear solution
(III)Q.C. Test Microbiological					
	Cultural characteristics observed after 24 – 48hrs. at 35-37°C.				
	MICROORGANISM (ATCC)		GROWTH		
	Candida albicans (10231)		good		
	Staphylococcus aureus (25923)		good		
	Staphylococcus aureus(6538)		good		
	Escherichia coli (25922)		good		
	Escherichia coli (8739)		good		
Precautions :	1. For Laboratory Use. 2. Follow proper, established laboratory procedures in handling and disposing of infectious materials.				
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:	It is recommended for sterility testing of pharmaceuticals in accordance with USP 2008.				
Storage :	Dehydrated medium- below 30°C Prepared medium– Between 2 to 8°C.				
Packing :	500 gm bottle				
Product profile:	Reconstitution	Quantity on Preparation (500g)	pH (25°C)	Supplement	Sterilization
B1168	18.00g/l	27.77L	6.9 ± 0.2	None	121°C / 15 minutes

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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