TECHNICAL SHEET

B1167	**DILUTING FLUID A**				
Formula					
Ingredients :	**gms/lit.**				
Peptic digest of animal tissue	1.00				
Final pH (at 25°C): 7.1± 0.2					
Directions :					
Suspend 1.0 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 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.					
QC Tests – (I)Dehydrated Medium					
Colour :			Cream to yellow		
Appearance :			Homogeneous Free Flowing powder		
(II)Rehydrated medium					
pH (post autoclaving/heating) :			7.1 ± 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			
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 isrecommended for sterility testing of pharmaceuticals in accordance with USP, 2011.				
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
B1167	1.00g/l	500.00L	7.1 ± 0.2	None	121^0C / 15 minutes

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