

TECHNICAL SHEET

BR002	Sterility Kit – II (FT, SCDM)	
Formula		
Ingredients:	gms/lit	
Sterile Alternative Thioglycollate Medium(B011)		
Casein enzymic hydrolysate	15.00	
Yeast extract	5.00	
Dextrose	5.50	
Sodium chloride	2.50	
L-Cystine	0.50	
Sodium thioglycollate	0.50	
Sterile Soyabean Casein Digest Medium (B040)		
Pancreatic digest of casein	17.00	
Papaic digest of soyabean meal	3.00	
Sodium chloride	5.00	
Dipotassium phosphate	2.50	
Dextrose	2.50	
Directions:		
<p>Label the ready to use BR002 bottle. Do not unscrew cap. remove the top of the screw cap. Disinfect the part of the rubber stopper which is now exposed. Draw sample with the sterile or disposable needle and syringe. Transfer the sample immediately into the BR002 bottle by puncturing the rubber stopper with the injecting needle. Keep the bottle in an upright position preferably in a biological safety cabinet, place an alcohol swab over the rubber stopper and insert the venting needle with filter through it (Use sterile venting needle. Insertion and withdrawal of the needle should be done in a straight line. discard the needle and mix the contents by gently inverting the bottle 2-3 times. Do Not vent the bottle for anaerobic cultures. Incubate at specified temperature for 18-24 hours and further for seven days.</p>		
Principle:		
<p>BR001 is ready to use sterile prepared media kit contains FAT medium and SCDM for Sterility checks in accordance with IP/USP/ EP/BP/JP. These are used for validation of the compliance of pharmacopeial raw materials, finished products and other articles. The Ready Prepared Media meet the requirements of Growth Promotion Test.</p> <p>1. Fluid Alternative Medium is used for sterility testing of turbid or viscous biological products.</p> <p>2. Soybean Casein Digest Medium is recommended for sterility checking and for studying total aerobic microbial count in verification of microbiological testing procedures employed for sterility checking. This medium is a highly nutritious medium used for cultivation of a wide variety of organisms.</p>		
(I) QC Tests		
Appearance:	Sterile Alternative Thioglycollate Medium and sterile Soyabean Casein Digest Medium in glass bottle.	
(II) Sterility test	Passes release criteria	

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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:	Fluid Alternative Medium is used for sterility testing of turbid or viscous biological products. Soybean Casein Digest Medium is recommended for sterility checking and for studying total aerobic microbial count in verification of microbiological testing procedures employed for sterility checking. Medium used for cultivation of a wide variety of organisms.
Storage:	Store between 15-25°C. Use before expiry date on the label.
Packing:	One kit contains 2 glass bottles each of 100 ml: sterile Fluid Thioglycollate Medium sterile Soyabean Casein Digest Medium recommended for injectibles

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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