



Sterility Method Validation Report

Description of the sample under validation:

Product Name:		Batch No:	
Total number of product containers/ vials use for validation:		A.R. No.:	
		β-lactamase enzyme lot no.	
Test Started On:		Test Completed On:	

Details of Culture Dilution:

S.No.	Test Organisms	ATCC No.	Culture suspension reference number	CFU / 0.1ml
1.	<i>Staphylococcus aureus</i>			
2.	<i>Pseudomonas aeruginosa</i>			
3.	<i>Clostridium sporogenes</i>			
4.	<i>Bacillus spizizenii</i>			
5.	<i>Candida albicans</i>			
6.	<i>Aspergillus brasiliensis</i>			
7.	Environmental Isolate-I (_____)			
8.	Environmental Isolate-II (_____)			

Details of Media, Diluting /Rinsing Fluid and Accessories:

S.No.	Media, Diluting / Rinsing Fluid	Sterile Media Lot No.
1.	Fluid Thioglycollate Medium (FTM)	
2.	Soyabean Casein Digest Medium (SCDM)	
3.	0.1 % Peptone water / Water for injection	

Details of Equipment:

S.No.	Equipment Description	Equipment ID	Validation Done on	Validation Due on
1.	Laminar Air flow Unit			
3.	BOD Incubator (30 - 35 °C)			
4.	BOD Incubator (20 - 25 °C)			
5.	Horizontal Autoclave			

Details of Membrane:

Membrane			
Make		Lot Number	



Sterility Method Validation Report

Observation of Positive Control Test:

Observation		<i>S. aureus</i>	<i>P. aeruginosa</i>	<i>Clostridium sporogenes</i>	EM Isolate – I	EM Isolate – II	Observed by
Days	Date						
1 st Day							
2 nd Day							
3 rd Day							

Acceptance Criteria: Growth should be observed within 3 Days.

Inference: Complies / Does not comply

Checked by:

Observation of Positive Control Test –

Observation		<i>Bacillus spizizenii</i>	<i>Candida albicans</i>	<i>Aspergillus brasiliensis</i>	EM Isolate – I	EM Isolate – II	Observed by
Days	Date						
1 st Day							
2 nd Day							
3 rd Day							
4 th Day							
5 th Day							

Acceptance Criteria: Growth should be observed within 3 Days in case of bacteria & environmental isolate, 5 days in case of *Aspergillus brasiliensis*.

Inference: Complies / Does not comply

Checked by:

Observation of Post GPT:

Observation		<i>S. aureus</i>	<i>Candida albicans</i>
Days	Date		
1 st Day			
2 nd Day			
3 rd Day			

Acceptance Criteria: Growth should be observed within 3 Days.

Inference: Complies / Does not comply

Checked by:

Analyzed by/ date:

Reviewed by/Date: