

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

Sterility Method Validation Report

Description of the sample under validation:

Product Name:	Batch No:	
Total number of product containers/	A.R. No.:	
vials use for validation:	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.	Staphylococcus aureus			
2.	Pseudomonas aeruginosa			
3.	Clostridium sporogenes			
4.	Bacillus spizizenii			
5.	Candida albicans			
6.	Aspergillus brasiliensis			
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	



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Observation of Bacteriostasis and Fungistasis Test (Positive product control):

Obser	rvation	S.aureus	P.aeruginosa	Clostridium	EM Isolate	EM Isolate	Observed
Days	Date			sporogenes	- I	– II	by
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:

NG=No Growth, G=Growth

Observation of Bacteriostasis and Fungistasis Test (Positive product control) -

Obser	vation	Bacillus	Candida	Aspergillus	EM Isolate	EM Isolate	Observed
Days	Date	spizizenii	albicans	brasiliensis	- I	– II	by
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 isolates & 5 days in case of *Aspergillus brasiliensis*.

Inference: Complies / Does not comply Checked by:

Observation of Product Control Test, Negative control Test and Negative control of Media:

Obse	ervation		Negative Product Control		Negative Control Negative C Test Negative C			Observed by
Days	Date	SCDM	FTM	SCDM	FTM	SCDM	FTM	
1st Day								
2 nd Day								
3 rd Day								
4 th Day								
5 th Day								
6 th Day								
7 th Day								
8 th Day								
9 th Day								
10 th Day								
11 th Day								
12 th Day								
13 th Day								
14 th Day								



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Observation of Positive Cont	rol	Test:
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Obse	ervation	S.	Р.	Clostridium	EM	EM Isolate	Observed
Days	Date	aureus	aeruginosa	sporogenes	Isolate – I	– II	by
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 –

Obse	ervation	Bacillus	Candida	Aspergillus	EM	EM Isolate	Observed
Days	Date	spizizenii	albicans	brasiliensis	Isolate – I	– II	by
1st 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		S. aureus	Candida albicans
Days	Date		
1st 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: