PERFORMANCE QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

Pre - Execution Approval

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				

PERFORMANCE QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

1.0 Objective:

- To establish documented evidence which will provide a High degree of assurance and reliability about the performance of the Steritest - Equinox.
- To determine that the Steritest - Equinox performs as intended by repeatedly running the system on its intended schedules and recording all relevant information and data. Results must demonstrate that performance consistently meets predefined specifications under normal conditions and where appropriate for worst case situations.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	**STERITEST - EQUINOX**
ID Number	**……**
Location	**Sterility Testing Room**

3.0 Performance Verification Checklist:

Verify the performance of all the critical process/functions as per their respective procedure. Refer Performance Verification Checklist as per Annexure - I.

4.0 Any Changes/Deviations identified during operating checks:

Refer Annexure – II.

5.0 Recommendations and Conclusions:

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……
……
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6.0 References:

Installation Qualification

Operational Qualification

Standard Operating Procedure

7.0 Annexure

Annexure - I : Performance Verification Checklist

Annexure - II : List of Changes / Deviation.

Annexure - III : Performance Qualification Report.

8.0 Abbreviations:

SOP : Standard Operating Procedure

Post execution approval:

	Name	Designation	Signature	Date
Compiled By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				

PERFORMANCE QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

Annexure - I
Checklist for Performance Verification

(A). Reference Instrument Verification: -

Instruments	Cat. Number	Serial Number	Last Calibration Date	Next Calibration
Incubators	------			

(B). Work area, Environment and Personnel Preparation Verification: -

Equipment		
Description	**Type / concentration of cleaning agent or Autoclaving Temperature / Time**	**Related SOP**
LAF		
Steritest Equinox pump body		
Steritest Equinox pump Head		
Canister Holder / Tubing		
Steritest Expendables Packaging		

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(B). Work area, Environment and Personnel Preparation Verification:

Personnel		
Personal Protective Equipment	**USE (Yes / No)**	**Related SOP**
Lab Coat		
Glasses		
Gloves		

(C). Microorganisms Preparation Work Sheet Verification:

Microorganisms Documentation		
Microorganisms	**ATCC Number**	**Type Of Preparation / Suspension Form**

(D). Material Disposal Work Sheet Verification:

Material For Disposal	Disposal Method	Related SOP
Media, Non Contaminated		
Steritest Device, Non Contaminated		
Rinse Fluid, Non Contaminated		
Covers, Papers, Non Contaminated		
Media Contaminated		
Steritest Devices, Contaminated		
Rinse Fluid, Contaminated		
Covers, Papers, Contaminated		

(E). Steritest Device Chemical Compatibility Verification:

Fluid Used for the Test	Catalogue Number (If applicable)	Lot Number (If applicable)	
Pressure Measurement System Used	**Type and/or Catalogue Number**	**Serial Number**	**Last Calibration Date**

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(E). Steritest Device Chemical Compatibility Verification:

Bubble Point Prior to Product Exposure					
Steritest Device Catalogue Number:					
Lot Number	**Test No.**	**Measured Bubble Point (mbar/psi)**		**Acceptance Criteria (mbar/psi)**	**Pass / Fail**
		Canister A	**Canister B**		

Product Exposure							
Steritest Device Catalogue Number:							
Contact Time:							
Test No.	**Visual Inspection Prior to product exposure**		**Acceptance Criteria**	**Visual Inspection at the end of the product exposure**		**Acceptance Criteria**	**Pass / Fail**
	Canister A	Canister B		Canister A	Canister B		
			No visible sign of damage on the membrane, canister and tubing			No visible sign of leaking (Drops coming out through the canister port and tubing)	

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(E). Steritest Device Chemical Compatibility Verification:

Steritest Device Rinsing								
Steritest Device Catalogue Number:								
Rinse Fluid:				Lot Number:				
Test No.	**Rinse Fluid Volume (ml)**		**Acceptance Criteria**	**Pass / Fail**	**Visual Inspection**		**Acceptance Criteria**	**Pass / Fail**
	Canister A	**Canister B**			**Canister A**	**Canister B**		
			Ability to filter all the rinse fluid without problem				No visible Sign of damage on the membrane canister and tubing	

Visual Inspection after Product Exposure								
Steritest Device Catalogue Number:								
Contact Time:								
Test No.	**Visual Inspection during the product exposure**		**Acceptance Criteria**	**Pass / Fail**	**Visual Inspection after product exposure**		**Acceptance Criteria**	**Pass / Fail**
	Canister A	Canister B			Canister A	Canister B		
			No visible sign of leaking (Drops coming out through the canister port and tubing)				No visible Sign of damage on the membrane canister and tubing	

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(E). Steritest Device Chemical Compatibility Verification:

Bubble Point after Product Exposure					
Steritest Device Catalogue Number:					
Lot Number	**Test No.**	**Measured Bubble Point (mbar/psi)**		**Acceptance Criteria (mbar/psi)**	**Pass / Fail**
		Canister A	Canister B		

(F). Sterility of Microbiological Media Verification:

Material Identification					
Type of Media	**Catalogue Number**	**FTM Upper Pink Zone before Incubation (≤ ½ or > 1/2)**	**Incubation**		
			Date	**Temperature (^{0}C)**	**Time (Days)**
Vented Needle Catalogue Number:					

Soyabean Casein Digest Medium Sterility Result				
Sample Number	**Incubation Date**	**Reading Date**	**Result After 14 Days**	
			No Growth (Pass)	**Growth (Fail)**

(F). Sterility of Microbiological Media Verification:

Fluid Thioglycollate Medium Sterility Result				
Sample Number	**Incubation Date**	**Reading Date**	**Result After 14 Days**	
			No Growth (Pass)	**Growth (Fail)**
Result of entire Test Activity: Growth and pink Zone ≤ 1/2				

(G). Microbiological Media Growth Promotion Verification: -

Material Identification			
Type of Media	**Catalogue Number**	**FTM Upper Pink Zone before Incubation (≤ ½ or > 1/2)**	**Incubation Temperature (^{0}C)**
Microorganisms used for the Test			ATCC No.

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(G). Microbiological Media Growth Promotion Verification:

Test Result			
Medium Type	**Medium Catalogue No.**	**Microorganisms**	**ATCC Number**

Incubation Temperature (^{0}C)	Incubation Time (Days)	Pharmacopoeia Specification (Days)

Medium Name (Catalogue Number)	Sample Number	Incubation Date	Result - Growth appear after				
			Reading Date	Reference Medium (1) (Days)	Medium being tested (Days)	Upper Pink Zone (ETM only)	
						≤ 1/2	≥ 1/2

Controls			
Medium Type	**Medium Catalogue No.**	**Microorganisms**	**ATCC Number**

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(G). Microbiological Media Growth Promotion Verification:

Control	Incubation Temperature (^{0}C) : _____			
	Incubation Time (Days) : _____			
	Incubation Date	**Reading Date**	**No Growth**	**Growth**

(H). Sterility of the Steritest Device(s) and Rinse Fluid (s) Verification:

Material Identification -

Steritest Device Catalogue Number: _____
Steritest Device Lot Number: _____

Type of Media	Catalogue Number	FTM Upper Pink Zone before Incubation (≤ ½ or > 1/2)	Incubation Temperature (^{0}C)

Fluid Name	What is the fluid used for in the internal SOP (Step Description + Rinse Fluid Volume)

Test Result -

Steritest Canister Number: _____							
Rinse Fluid Catalogue Number: _____							
Steritest Lot Number	**Incubation Date**	**Result After 14 days incubation**					
		Reading Date	**First Canister (SCD)**		**Second Canister (FTM)**		
			No Growth	**Growth**	**No Growth**	**Growth**	**Pink Zone ≤ 1/2**

PERFORMANCE QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

(I). Sterility of the Steritest Device(s) and Rinse Fluid (s) Verification: Bacteriostasis and Fungistatis - (Material Identification)

Material Identification			
Type of Media	**Catalogue Number**	**FTM Upper Pink Zone before Incubation (≤ ½ or > 1/2)**	**Incubation Temperature (^{0}C)**

Microorganisms used for the Test	ATCC No.

Steritest Device Catalogue Number	Steritest Device Lot Number

Fluid Name	Fluid Catalogue Number	What is the fluid used for in the internal SOP (Step Description + Rinse Fluid Volume)

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

PERFORMANCE QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

(I). Sterility of the Steritest Device(s) and Rinse Fluid (s) Verification: Bacteriostasis and Fungistatis - (Test Result)

Steritest Catalogue Number: _____
Rinse Fluid Reference: _____
Microorganisms: _____
ATCC Number: _____
Incubation Temperature (^{0}C): _____
Incubation Time: _____

Steritest Lot Number	Rinse Fluid Lot Number	Incubation Date	Result			
			Reading Date	Growth observed After (Days)	Growth within specification	Pink Zone ≤ ½ (FTM only)

Steritest Catalogue Number: _____
Rinse Fluid Reference: _____
Microorganisms: _____
ATCC Number: _____

	Media	Incubation Date	Reading Date	No Growth	Growth	Pink Zone ≤ ½ (FTM only)

PERFORMANCE QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

(I). Sterility of the Steritest Device(s) and Rinse Fluid (s) Verification: - Bacteriostasis and Fungistatis - (Test Result)

Steritest Catalogue Number: _____

Rinse Fluid Reference: _____

Microorganisms: _____

ATCC Number: _____

	Time	Incubation Date	Reading Date	Growth	No Growth	Pink Zone ≤ ½ (FTM only)
	Start of Test					
	End of Test					

(J). Pharmaceutical Product Verification: (Bacteriostasis and Fungistatis)

Description	Catalogue Number	Lot Number	FTM Upper Pink Zone Before Incubation (≤ ½ or ≥ ½)	Incubation Temperature (^{0}C)

PERFORMANCE QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

(J). Pharmaceutical Product Verification: (Bacteriostasis and Fungistatis)

Microorganisms used for the Test	ATCC No.

Test Result:

Steritest Catalogue Number: _____

Steritest Lot Number: _____

Microorganisms: _____

ATCC Number: _____

Medium: _____

Incubation Temperature (^{0}C): _____

Incubation Time: _____

Article Name	Incubation Date	Result			
		Reading Date	Growth Appears After (Days)	Growth within specification	Pink Zone $\leq$ ½ (FTM only)

PERFORMANCE QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

(J). Pharmaceutical Product Verification: (Bacteriostasis and Fungistatis)

Controls:

Steritest Catalogue Number: _____

Rinse Fluid Reference: _____

Microorganisms: _____

ATCC Number: _____

Medium: _____

	Incubation Date	Reading Date	No Growth	Growth	Pink Zone ≤ ½ (FTM only)

Steritest Catalogue Number: _____

Rinse Fluid Reference: _____

Microorganisms: _____

ATCC Number: _____

Medium: _____

	Time	Incubation Date	Reading Date	Growth	No Growth	Pink Zone ≤ ½ (FTM only)
	Start of Test					
	End of Test					

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(K). System Operating Procedure Verification:

Materials Identification:

Steritest Catalogue Number: _____
Steritest Device Lot Number: _____

Type of Media	Catalogue Number	FTM Upper Pink Zone before Incubation (≤ ½ or > 1/2)	Incubation Temperature (^{0}C)

Fluid Name	Fluid Catalogue Number	What is the fluid used for in the internal SOP (Step Description + Rinse Fluid Volume)

Steritest Cat. Number: _____
Article Catalogue Number: _____

Steritest Lot Number	Article Lot Number	Incubation Date	Reading Date	Result After 14 days of incubation				
				First Canister (SCD)		Second Canister (FTM)		
				No Growth	Growth	No Growth	Growth	Pink Zone ≤ 1/2

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(K). System Operating Procedure Verification:

Automatic Mode:

SOP Name: ____

Step Number	Type	Speed	Times (s)	Comments

Step Number	Acceptance Criteria	Criterion Met (Yes/No)	Pass / Fail
	Appears properly on the Steritest Equinox Pump screen and conforms to the SOP loaded in the Steritest Equinox Pump		
	Appears properly on the Steritest Equinox Pump screen and conforms to the SOP loaded in the Steritest Equinox Pump		
	Appears properly on the Steritest Equinox Pump screen and conforms to the SOP loaded in the Steritest Equinox Pump		
	Appears properly on the Steritest Equinox Pump screen and conforms to the SOP loaded in the Steritest Equinox Pump		
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	Appears properly on the Steritest Equinox Pump screen and conforms to the SOP loaded in the Steritest Equinox Pump		
	Appears properly on the Steritest Equinox Pump screen and conforms to the SOP loaded in the Steritest Equinox Pump		

Note:

Remarks: - Performance verification of Steritest Equinox **-** Complies / Does not comply.

Verification Done By: -

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Annexure - II

List of Changes / Deviations

S.No.	Description of Change / Deviations	Justification based on impact analysis

Verified By:

Approved By: