



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

OPERATIONAL QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

Pre - Execution Approval

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



OPERATIONAL QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

1.0 Objective:

- To determine that the equipment operates according to specifications, and to record all relevant information's and data to demonstrate its functions as intended for.

2.0 Scope:

Scope is limited to the following

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

3.0 Checklist for Operational verification:

Operation of Steritest - Equinox is verified for the compliance with the critical parameters mentioned in the Functional Specification. Sequentially prepare the list of operating checks specifying critical parameters, perform them as per operating procedure as mentioned in the vender operating manual & document the same in the attached check list (Annexure - I).

4.0 Any Changes/Deviations identified during operating checks:

Refer Annexure – II

5.0 Identification & preparation of Standard Operating Procedures:

Prepared the SOP for Operation, Cleaning and Calibration of Steritest - Equinox using the actual feedback from the operation checks and vendor-operating manual. The preventive maintenance procedure and schedule shall be applicable as per Annual Maintenance Contract of QC Instrument.

<u>S. No.</u>	<u>SOP Title</u>	<u>SOP Number</u>
1.	Operation, Cleaning and Calibration Of Equinox System



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6.0 Training

The List of QC (Microbiology) person trained during the operation qualification of Steritest - Equinox is listed as per Annexure - III.

7.0 Recommendations and Conclusions:

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8.0 References:

Installation Qualification
Operating Manual submitted by the Vendor.

9.0 Annexure

Annexure - I : Checklist for Operational Verification.
Annexure - II : List of Changes / Deviation.
Annexure - III : Training Detail

10.0 Abbreviations:

SOP : Standard Operating Procedure
QC : Quality Control

Post execution approval:

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



OPERATIONAL QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

Annexure - I

Checklist for Operational Verification

S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
A.	Verification of Reference Instrument			
1.	Steritest gauge	-----		
a.	Catalogue no.		
b.	Serial No.	Not applicable		
c.	Last Calibration date	Not applicable		
2.	Balance	-----		
a.	Catalog Number	Not applicable		
b.	Serial No.	Not applicable		
B.	Verification of Work area, Environment and Personnel Preparation			
1.	Type / concentration of cleaning agent use for LAF	Not applicable		
2.	Type / concentration of cleaning agent use for Steritest Equinox pump body	Not applicable		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
B.	Verification of Work area, Environment and Personnel Preparation			
3.	Autoclaving temperature / time use for Steritest Equinox pump Head	Not applicable		
4.	Autoclaving temperature / time use for Canister holder / Tubing	Not applicable		
C.	Verification of Steritest Equinox Pump PC software (Ability to change the password)			
1.	Password	Not possible to create a password of 4 character or less		
		Not possible to create a password of 11 character or more		
		Possible to create a password of 5 character long		
		Possible to create a password of 10 character long		
		Not possible to create a password containing a forbidden character		
		Possible to create a customer password that is 5 to 10 character long		
		Not possible to access the Steritest software by using an in correct password		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
D.	Verification of Steritest Equinox Pump PC software (Ability to create an SOP)			
1.	Creation of SOP	Not possible to create a SOP with blank title		
		Not possible to create a SOP title of 13 character		
		Not possible to create a SOP title containing a forbidden character		
		Possible to create a SOP title of 12 character		
		Confirm that step 1 is automatically generated in the “ Handling Step” window and that the “Timer” filed shows “0” (OFF)		
		In the “Type” field , the seven available items are : “Dilution”, “Dissolution”, “Prewetting”, “Filtration”, Rinsing”, “ Media transfer”, and “Other”		



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S.No.	Operating Parameters	Function /Acceptance Criteria	Observation	Remarks
D.	Verification of Steritest Equinox Pump PC software (Ability to create an SOP)			
1.	Creation of SOP	Not possible to enter "0" in the " Speed" Field (Error message)		
		Not possible to enter "151" in the " Speed" Field (Error message)		
		Possible to enter "1" in the " Speed" Field		
		Possible to enter "150" in the " Speed" Field		
		Not possible to enter "1000" in the " Timer" Field (Only "100" is displayed)		
		Possible to enter "999" in the " Timer" Field		
		Not possible to enter "10.1" in the " Timer" Field		
		Possible to enter "0.5" in the " Timer" Field		
		Not possible to enter "0.4" in the " Timer" Field (Error message)		
		The SOP in the software main screen are displayed in blue in the " Steritest " Column		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
E.	Verification of Steritest Equinox Pump PC software (Ability to perform the “ Synchronize”) function			
1.	Synchronize function on the Steritest Equinox Pump PC software	SOP Synchronization is successful (“Successful Transfer” message)		
		The SOP in the software main screen are displayed in green in the “Steritest” column		
		Configuration name		
2.	Synchronize function on the Steritest Equinox Pump	All the SOP listed in the “ Workfile” column of the software are present in the pump		
		SOP content in the pump conforms to the SOP content displayed in the PC software		
F.	Verification of Steritest Equinox Pump PC software (Ability to perform the “ Import” function)			
1.	Import function on the Steritest Equinox Pump PC software	Backup file is created		
		The SOP content in the “Backup Management” window is exactly the same as the SOP content on the print out		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
F.	Verification of Steritest Equinox Pump PC software (Ability to perform the “ Import” function)			
1.	Import function on the Steritest Equinox Pump PC software	The SOP content present in the pump is exactly the same as the SOP content on the back up file printout		
G.	Verification of Steritest Equinox Pump PC software (Ability to perform the “ Export” function)			
1.	Export function on the Steritest Equinox Pump PC software	In the main screen, the SOP “ Test creation” is in red in the “Steritest” column		
		The “Export” command is successful		
		The speed is “99” in the “ Test creation” SOP step 1 in the Work file column		
		The speed is “150” in the “ Test creation” SOP step 1 in the Steritest column		
		The speed value in the Steritest Equinox pump is “150”		
H.	Verification of Steritest Device Identification			
1.	Catalogue Number	Not applicable		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
I.	Verification of Steritest Equinox pump Rotation and speed Setting			
1.	Steritest Equinox pump Rotation and speed Setting	The pump head rotate clockwise		
		Possible to display any value from “1” to “150” by turning the knob clockwise		
		Pump head rotation speed increases when moving from “1” to “150”		
		Not possible to move from “150” to “1” when turning the knob clockwise.		
		Possible to display any value from “150” to “1” by turning the knob counterclockwise		
		Pump head rotation speed decreases when moving from “150” to “1”.		
		Not possible to move from “1” to ‘150” when turning the knob counterclockwise.		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
J.	Verification of Steritest Equinox pump Footswitch			
1.	Steritest Equinox pump Footswitch (Pulse Mode)	The pump runs while the footswitch is depressed		
		The pump stops when the footswitch is un - pressed		
2.	Steritest Equinox pump Footswitch (Two way mode)	Depressing the footswitch once briefly starts the pump		
		The pump continues to run after un - pressing the footswitch		
		Depressing the footswitch briefly once again stop the pump		
K.	Verification of Steritest Equinox pump Counter (Timer Function) in the Manual Mode			
1.	Ist scale "Timer" Value : 10 Sped Value: 1 (Three Trial of Timer Display 10 sec)	11 sec ± 1 second		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
K.	Verification of Steritest Equinox pump Counter (Timer Function) in the Manual Mode			
1.	1st scale "Timer" Value : 10 Sped Value: 1 (Three Trial of Timer Display 10 sec)	When the pump head rotates, The "Timer" value blinks.		
		When the pump head stop rotating, the "Timer" value stops blinking		
2.	2nd scale "Timer" Value: 50 Sped Value: 75 (Three Trial of Timer Display 50 sec)	57 sec ± 2 second		
		When the pump head rotates, The "Timer" value blinks.		
		When the pump head stop rotating, the "Timer" value stops blinking		
		1 minute 54 sec ± 3 second		
3.	3rd scale "Timer" Value : 100 Sped Value: 150 (Three Trial of Timer Display 100 sec)	When the pump head rotates, The "Timer" value blinks.		
		When the pump head stop rotating, the "Timer" value stops blinking		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
L.	Verification of Steritest Equinox pump Counter (Timer Function) in the Automatic Mode			
1.	1st scale "Timer" Value : 10 Sped Value: 1 (Three Trial of Timer Display 10 sec)	11 sec ± 1 second		
		When the pump head rotates, The "Timer" value blinks.		
		When the pump head stop rotating, the "Timer" value stops blinking		
2.	2nd scale "Timer" Value: 50 Sped Value: 75 (Three Trial of Timer Display 50 sec)	57 sec ± 2 second		
		When the pump head rotates, The "Timer" value blinks.		
		When the pump head stop rotating, the "Timer" value stops blinking		
3.	3 rd scale "Timer" Value : 100 Sped Value: 150 (Three Trial of Timer Display 100 sec)	1 minute 54 sec ± 3 second		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
L.	Verification of Steritest Equinox pump Counter (Timer Function) in the Automatic Mode			
3.	3rd scale "Timer" Value : 100 Sped Value: 150 (Three Trial of Timer Display 100 sec	When the pump head rotates, The "Timer" value blinks.		
		When the pump head stop rotating, the "Timer" value stops blinking		
M.	Verification of Steritest Device Installation			
1.	Steritest Equinox pump serial Number	Not applicable		
2.	Steritest Device Catalogue number	Not applicable		
3.	Steritest Device Lot Number	Not applicable		
4.	Steritest Device Installation	Possible to properly set up the Steritest Device on the pump		
		Possible to start the pump without obtaining an error message.		
		Possible to transfer 200 ml of purified water through the Steritest Device Tubing.		
		Visual Inspection of the tubing shows no signs of damage and / or leaking.		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
N.	Verification of Steritest Equinox Pressure Sensors			
1.	Steritest Equinox pump serial Number	Not applicable		
2.	Steritest Device Catalogue number	Not applicable		
3.	Steritest Device Lot Number	Not applicable		
4.	Sensor Verification Kit Value (Psi) (Top Sensor)	Below 53 psi		
5.	Sensor Verification Kit Value (Psi) (Bottom Sensor)	Below 53 psi		
O.	Verification of Steritest Equinox Pump Automatic Pressure Control Function			
1.	Steritest Equinox pump serial Number	Not applicable		
2.	Steritest Device Catalogue number	Not applicable		
3.	Steritest Device Lot Number	Not applicable		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
O.	Verification of Steritest Equinox Pump Automatic Pressure Control Function			
1.	Steritest Equinox pump serial Number	Not applicable		
2.	Steritest Device Catalogue number	Not applicable		
3.	Steritest Device Lot Number	Not applicable		
4.	Automatic Pressure Control Function (Top Sensor Tubing)	Pressure Control Symbol is displayed in the mode screen when the pump head is closed		
		The automatic pressure control start and a barograph is display on the mode screen		
		The automatic pressure control start and the pump speed decreases		
		The automatic pressure control stop the pump if the pressure is not decreased		
		The "Pressure control out of limit" screen is displayed 20 seconds later after the pump stops		
		The pump head restart turning when the pressure has been decreased		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
O.	Verification of Steritest Equinox Pump Automatic Pressure Control Function			
5.	Automatic Pressure Control Function (Bottom Sensor Tubing)	Pressure Control Symbol is displayed in the mode screen when the pump head is closed		
		The automatic pressure control start and a barograph is display on the mode screen		
		The automatic pressure control start and the pump speed decreases		
		The automatic pressure control stop the pump if the pressure is not decreased		
		The "Pressure control out of limit" screen is displayed 20 seconds later after the pump stops		
		The pump head restart turning when the pressure has been decreased		
P.	Verification of Steritest Equinox Pump Pressure Sensor Safety System			
1.	Steritest Equinox pump serial Number	Not applicable		
2.	Steritest Device Catalogue number	Not applicable		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
P.	Verification of Steritest Equinox Pump Pressure Sensor Safety System			
3.	Steritest Device Lot Number	Not applicable		
4.	The Pressure in the canister is close to the canister maximum guaranteed pressure	An alarm beep is heard and the display reads "High Pressure"		
5.	The Pressure in the canister is reach the canister maximum guaranteed pressure	An alarm beep is heard and the display reads "Over Pressure Alarm"		
	Disappear of "Over Pressure Alarm"	The "Over Pressure Alarm" message disappears when the pump head is opened and the pressure in the testing canister drops		
Q.	Verification of Steritest Membrane Integrity			
1.	Code number of Pressure Measurement system Used	Not applicable		
2.	Type and/or Catalogue Number	Not applicable		
3.	Serial Number	Not applicable		
4.	Last Calibration date	Not applicable		
5.	Steritest Device Catalogue No.	Not applicable		
6.	Lot No.	Not applicable		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
Q.	Verification of Steritest Membrane Integrity			
7.	Measured Bubble Point (mbar/psi) (Canister A)	Minimum 30 psi		
8.	Measured Bubble Point (mbar/psi) (Canister B)	Minimum 30 psi		
R.	Verification of Steritest Device Splitting Capability			
1.	Steritest Equinox Pump Serial Number	Not applicable		
2.	Balance Used	Not applicable		
3.	Type and / or Catalogue Number	Not applicable		
4.	Serial Number	Not applicable		
5.	Device Lot Number	Not applicable		
6.	Weigh of Canister A	Not applicable		
7.	Weigh of Canister B	Not applicable		
8.	% of splitting difference	% Diff $\leq \pm 10 \%$		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
S.	Verification of SOP content and Steps in Automatic Mode			
1.	Steritest Equinox Pump Serial Number	Not applicable		
2.	Steritest Device Catalogue Number	Not applicable		
3.	Lot Number	Not applicable		
4.	Step - 1 Dilution	“Dilution” step display after selecting the “Test – Step’ SOP		
		The “Dilution” step runs at speed “50” with timer at “20”		
		At the end of the “Dilution” step, the pump stop.		
5.	Step - 2 Dissolution	After pressing on the ‘Next/Back” button “Dissolution” step displays.		
		The “Dissolution” step runs at speed “60” with timer at “20”		
		At the end of the “Dissolution” step the pump stops.		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
S.	Verification of SOP content and Steps in Automatic Mode			
6.	Step - 3 Pre - Wetting	After pressing on the "Next/Back" Button, "Prewetting" Step displays		
		The "Prewetting" Step runs at speed "100" with timer at "10"		
		At the end of the "Prewetting" step the pump stops		
7.	Step - 4 Filtration	After pressing on the "Next/Back" Button, "Filtration" Step displays		
		The "Filtration" Step runs at speed "75" with timer at "10"		
		At the end of the "Filtration" step the pump stops		
8.	Step - 5 Rinsing	After pressing on the "Next/Back" Button, "Rinsing" Step displays		
		The "Rinsing" Step runs at speed "75" with timer at "15"		
		At the end of the "Rinsing" step the pump stops		



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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
S.	Verification of SOP content and Steps in Automatic Mode			
9.	Step - 6 Media Transfer	After pressing on the “Next/Back” Button, “Media Transfer” Step displays with comment “TSB”		
		The “Media Transfer” Step runs at speed “75” with timer “OFF”		
		At the end of the “Media Transfer” step the pump stops		
10.	Step - 7 Other	After pressing on the “Next/Back” Button, “Other” Step displays with comment “FTM”		
		The “Other” Step runs at speed “25” with timer “OFF”		
		This “Media Transfer” step stop after stopping the pump		
11.	End of test	The pump head open after pressing “Next/Back” button		



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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:



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Annexure - III

Training Detail

S.No.	Name of Trainee	Name of Trainer

Verified By:

Approved By: