INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

Pre - Execution Approval

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

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

1.0 Objective:

The purpose of installation qualification is as follows

- To provide documented evidence that the mentioned Steritest - Equinox is installed as per design.
- To ensure that the Steritest - Equinox installed confirms to purchase specifications and manufacturer literature, and to document the information that the Steritest - Equinox meets the specification.

2.0 Scope:

Scope is limited to the following

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

3.0 Equipment / System Description:

Steritest - Equinox is a uniquely designed peristaltic pump used with Steritest canisters for sterility testing of products. With the Steritest closed system, the risk of false positive result is drastically reduced. The broad capabilities of the Steritest canister set make it possible to test a wide verity of products including:

- Large and small volume parenteral solution in glass or plastic bottles, collapsible bags, ampoules and vials.
- Prefilled syringes.
- Lyophilized and other soluble products in ampoules and vials.
- Antibiotics in ampoules or vials.

A product is transferred directly from the drug container through Steritest sterile tubing, which splits the products into equal portions, to the Steritest canister without exposure to air – born contaminants.

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

4.0 Checklist for Preinstallation verification:

The purpose of the checklist is to confirm the availability of required documents for installation and to verify the availability of components and parts as per the approved purchase order in presence of the technical personnel of the vendor.

Preinstallation verification checklist is enclosed as Annexure - I.

5.0 Checklist for Installation verification:

Installation verification checklist is enclosed as Annexure - II.

6.0 Any Changes identified towards equipment design / lay out.

Refer Annexure - III.

7.0 Recommendations and Conclusions:

8.0 References:

Copy of Purchase order

Packing list supplied by vendor (Not applicable).

List of spares (Not applicable).

Installation Qualification submitted by vendor.

Impact Assessment analysis.

9.0 Annexure

Annexure - I : Check list for Preinstallation Verification.

Annexure - II : Check list for Installation Verification.

Annexure - III : List of Changes / Deviation.

Annexure - IV : Installation Qualification Submitted by the vendor.

Annexure - V : Impact Assessment Analysis.

Annexure - VI : Summary Report of Installation Qualification

Annexure - VII : Copy of Purchase order

10.0 Abbreviations:

IQ : Installation Qualification

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

Post execution approval:

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

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

Annexure - I

Checklist for Preinstallation Verification

S.No.	Main Components Accessories / Documents	Code / Doc No.	Actual	Remarks
1.	Purchase Order No.	……		
2.	Vendor's Name	M/s Millipore		
3.	Instrument Make	Millipore		
4.	Instrument Model No.	Steritest - Equinox		
5.	Instrument Manual	Instrument Manual submitted by the vendor		

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

Annexure - II

Checklist for Installation Verification

S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
a.	**Verification of reference documents worksheet**			
1.	User guide Equinox	Doc. Number ……., Rev. …., date ….		
2.	Sterility Testing SOP Transfer - User Guide	Doc. Number …….. Rev. …., date - …..		
3.	Startup document for Equinox	Doc. Number …….. Rev. - new, date - ……		
b.	**Verification of utilities and operating environment requirements**			
1.	Installation location	Sterility Testing Room		
2.	Room Class/Grade	Grade B		
3.	Electrical Requirement	230 V ± 10 %; 50 Hz		
4.	Temperature	16^0C to 30^0C		
5.	Relative Humidity	Less than 90 % RH (Non condensing)		
6.	Expendable Storage Conditions	Room temperature, No direct sunlight exposure		

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

S.No.	System Data	Acceptance Criteria	Actual	Remarks
c.	**Verification of work area, equipment and personnel preparation work sheet**			
1.	Type/concentration of cleaning agent used for Laminar air flow unit	70/30 or IPA/H_2O mixture or Sterillium		
2.	Type/concentration of cleaning agent used for Steritest Equinox Pump Body	70/30 or IPA/H_2O mixture or Sterillium		
3.	Type/concentration of cleaning agent used for Steritest Equinox Pump Head Rotar	70/30 or IPA/H_2O mixture or Sterillium		
4.	Type/concentration of cleaning agent used for Steritest Equinox Pump Head cover	70/30 or IPA/H_2O mixture or Sterillium		
5.	Autoclaving Temperature and time for Drain Tray/ Tubing	Autoclave at 121^0C / 45 minute		
6.	Autoclaving Temperature and time for Bottle Holder	Autoclave at 121^0C / 45 minute		
7.	Personnel proactive equipment	Personnel should wear lab coat, glasses and gloves		

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

S.No.	System Data	Acceptance Criteria	Actual	Remarks
d.	**Verification and identification of the Steritest Equinox pump**			
1.	Steritest Equinox Pump	Should Be present (Cat. Number - …….)		
2.	Knob	Should Be present		
3.	Pump Head Cover	Should Be present (Cat. Number - ……)		
4.	Silicon tubing for drain tray	Should Be present (Cat. Number - …….)		
5.	Bottle holder	Should Be present (Cat. Number - …….)		
6.	Power cable for Europe	Should Be present (Cat. Number - …….)		
7.	Power cable for N. America	Should Be present (Cat. Number - TQ00ELKIT)		
8.	PC connecting cable RJ 45	Should Be present		
9.	Drain Tray	Should Be present (Cat. Number - …..)		

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

S.No.	System Data	Acceptance Criteria	Actual	Remarks
d.	**Verification and identification of the Steritest equinox pump**			
10.	Power Supply Box	Should Be present (Cat. Number - …….)		
11.	User Guide for Steritest Equinox pump	Should Be present (Cat. Number - ……)		
12.	User Guide for Steritest Equinox pump PC software	Should Be present (Cat. Number - …..)		
13.	Steritest Equinox pump PC software on CD - ROM with its User Guide	Should Be present (Cat. Number - ……)		
14.	Steritest Equinox Footswitch (Optional)	Should Be present (Cat. Number - ……) Sr No. ……		
e.	**Verification of the Steritest equinox pump assembly and start up**			
1.	Setting of Steritest Equinox pump	Set up in accordance with the Steritest Equinox pump user guide		
2.	Setting of optional accessories	Set up in accordance with the test method		

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

S.No.	System Data	Acceptance Criteria	Actual	Remarks
e.	**Verification of the Steritest equinox pump assembly and start up**			
3.	Switch power supply ON	Red light switch illuminates		
		Startup screen appears and the pump head is in "OPEN" position		
4.	Auto Test	"Auto Test--------OK" is display on the startup screen		
5.	Initializing	"Initializing -------OK" is display on the startup screen		
f.	**Verification of the Steritest equinox information menu**			
1.	Serial Number	Serial Number displayed on the screen same as the serial number on the certificate of conformity		
		Serial Number displayed on the screen same as the serial number on the back plate of the pump		
2.	SOP update date	Displayed on the Steritest equinox pump screen		

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

S.No.	System Data	Acceptance Criteria	Actual	Remarks
g.	**Verification of the Steritest equinox pump date and time configuration**			
1.	Date	Possible to enter current date in the pump		
2.	Time	Possible to enter current time in the pump		
h.	**Verification of the Steritest equinox pump - head protective cover safety system**			
1.	Initialization Phase	Message “ERROR (cover)” is displayed		
2.	Manual Testing Mode	Message “Cover not present. Put cover and restart” appears.		
		The pump - head does not rotate after pressing the knob		
3.	Automatic Testing Mode	Message “Cover not present. Put cover and restart” appears.		
		The pump - head does not rotate after pressing the knob		

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

S.No.	System Data	Acceptance Criteria	Actual	Remarks
i.	**Verification of PC software installation**			
1.	Software installation	"The install Shield Wizard has successfully installed Steritest" is displayed		
		The *Steritest* icon is displayed on the computer desktop		
j.	**Verification of the installation of correct version of the PC software**			
1.	Software installation of Correct Version	The PC Software version number displayed by the Sterility Testing SOP Transfer Software matches the version number on the CD		
k.	**Verification of the direct connection between the Steritest Equinox pump and the computer**			
1.	Direct connection between the Steritest Equinox pump and the computer	The PC Software displays the pump IP address ……		
		The PC Software displays the "Status: OK" message		

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

S.No.	System Data	Acceptance Criteria	Actual	Remarks
k.	**Verification of the direct connection between the Steritest Equinox pump and the computer**			
1.	Direct connection between the Steritest Equinox pump and the computer	The SOP in the pump match the SOP on the PC (in the "Steritest" column)		
		The SOP in the "Steritest" column are green if they have previously been synchronized, or are not present if the Steritest Equinox pump has never been used		
B.	**Location suitability**			
1.	Location	Should be place in Sterility Testing Room Under Laminar Air Flow Unit		
C.	**Utilities**			
1.	Electrical Supply	230 ± 10 %; 50 Hz, supply should be provided		

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

S.No.	System Data	Acceptance Criteria	Actual	Remarks
D.	**Safety**			
1.	Not Applicable	Not Applicable		
E.	**MOC Certificates**			
1.	Not Applicable	Not Applicable		
F.	**Calibration Certificates**			
1.	Not Applicable	Not Applicable		
G.	**Testing Certificates**			
1.	Not Applicable	Not Applicable		
H.	**Drawing Details**	**Drawing No.**		
1.	Not Applicable	Not Applicable		

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

Annexure - III

List of Changes / Deviations

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

Verified By:

Approved By:

INSTALLATION QUALIFICATION PROTOCOL FOR STERITEST EQUINOX

Annexure - VI

Summary Report of Installation Qualification

Checks	Observations (Yes / No)	Reviewed By Sign / Date
All test procedures executed and verified as per the protocol.		
All criteria set forth in the installation qualification were met.		
Deviation if any		

Summary:

_____

_____

_____

_____

_____

_____

Summary Report Prepared By:

Date & Sign