



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: SOP for Cleaning and operation procedure of steritest equinox pump and its accessories

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 6

1.0 Objective

To lay down the cleaning and operating procedures for steritest equinox pump and its accessories.

2.0 Scope

This Standard Operating Procedure is applicable to Quality control department.

3.0 Responsibility

Executive/Sr.Executive-QC : Responsible for following the cleaning and operating procedures for steritest equinox pump and its accessories.

Head-QC/Designee : Shall be responsible for the compliance of this SOP

4.0 Abbreviations and Definitions

SOP : Standard Operating Procedure

No. : Number

QC : Quality control

5.0 Procedure

5.1 General instructions

5.1.1 Follow the Sop “ Standard operating and cleaning procedure of Dynamic Pass Box” for material movement through pass boxes.

5.1.2 Enter the aseptic area as per Sop “Entry and exit in Aseptic area of microbiology Laboratory.”

5.1.3 Prepare the isolator as per Sop “Standard operating, monitoring and cleaning procedure of Isolator”.

5.1.4 The environmental monitoring during the sterility testing should be carried out as per Sop “Environmental monitoring in Microbiology section”.

5.1.5 Disinfect gloved hands with validated disinfectant at regular intervals.

5.1.6 Discard used material as per Sop “ Disposal of used Microbial media, cultures and contaminated materials”.



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5.1.7 Area should be cleaned as per Sop “Cleaning, Sanitization and Disinfection in Microbiology laboratory”.

5.18 Collect all material required to perform the test on stainless steel trolley before start of test.

5.1.9 Do not use gas burner inside the isolator.

5.2 **Cleaning the Steritest Equinox Pump.**

5.2.1 Clean the head of the pump and mop it with a sterile lint free cloth soaked in validated disinfectant.

5.2.2 Similarly clean the body of the pump

5.2.3 After each operation clean the drain tray and drain tube with extra solution and then sterilize it at 121°C for validated period of time.

5.2.4 Autoclave bottle holder once a month or whenever there is spillage of media over the bottle holder

5.3 **Assembling the Steritest Equinox Pump accessories:**

5.3.1 Arrange material required in isolator after disinfecting their surface with validated disinfectant.

5.3.2 Open steripouch packet and take out bottle holder from it.

5.3.3 On the left side of the Steritest Equinox Pump handle insert bottle holder in bottle holder mount housing until it contacts the workbench and the jug is firmly seated in one of the two slots on top of the housing.

5.3.4 Open steripouch packet and take out drain tray with silicone drain tubing from it.

5.3.5 On the right side of the Steritest Equinox Pump insert drain tray onto its support until it clicks securely into place. The pump carrying handle is used to ensure correct positioning.

5.3.6 Place the other end of the tubing in a waste container placed under the isolator. Avoid back flow of fluid and reverse pressure into the drain tray by making sure that the tubing does not touch the liquid in the waste container and that the waste container is open or correctly vented

5.3.7 Optional foot switch



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5.3.7.1 Connect the foot switch to its connection port on the power supply unit

5.3.7.2 Place the foot switch underneath the isolator.

5.3.7.3 Connect the Steritest Equinox Pump connection cable and power cable to the power supply unit to their respective slots.

5.4 Operation of Steritest Equinox Pump

5.4.1 Plug the electrical cord into power supply.

5.4.2 Press the 'ON' / 'OFF' button on the Steritest Equinox Pump switch.

5.4.3 Switch 'ON' the power supply unit with its 'ON' / 'OFF' switch.

5.4.4 The start up screen appears and the pump head opens.

5.4.5 Check the cover is installed on the drain tray and fix the canisters as follows.

5.4.5.1 Unpack the desired cannisters aseptically and place the canisters on the drain tray.

5.4.5.2 Install the tubing in the pump head by gently pulling the tubing and engaging it fully in the cover.

5.4.5.3 Check that the two tubing hoses are positioned on either side of the boxes on the right and left side of the cover.

5.4.5.4 Slide the tubing from left to right and right to left, to ensure that it is correctly positioned.

5.4.5.5 Close the pump head by pressing the 'OPEN' / 'CLOSE' button.

5.4.5.6 Select the manual or automatic testing mode by turning the knob to highlight the mode. Press the knob to confirm the selection.

5.4.5.7 Operate the Steritest Equinox Pump in manual mode as follows

5.4.5.8 Turn the knob clockwise or anticlockwise to increase or decrease the rotation speed of the pump respectively

5.4.5.9 Press the knob or footswitch to start or stop the pump.

5.4.5.10 To activate the timer press and hold the knob until the buzzer rings and the word 'Timer' blinks on the display



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- 5.4.5.11 Release the knob and turn it to program the timer value. Confirm by briefly pressing the knob. The word 'Timer' stops blinking and new value is memorized.
- 5.4.5.12 Press the knob to start the pump. The pump will stop automatically after the programmed timer value has elapsed.
- 5.4.5.13 In timer mode when the pump head is rotating the timer value blinks. To deactivate the timer mode proceed in the same way as it activated and program the value to 0.
- 5.4.5.14 To stop the pump before the programmed timer value has elapsed press the knob or footswitch. Pump stops and two options appear i.e. 'continue' & 'abort' highlight the wanted option press the knob to confirm.
- 5.4.5.15 If 'continue' is confirmed pump is restarted and continue the countdown.
- 5.4.5.16 Select 'abort' to reset the timer value.
- 5.4.6 Operate the pump in automatic mode as follows
- 5.4.6.1 When pump stops press the 'OPEN' / 'CLOSE' button to open it.
- 5.4.6.2 Press and hold down the 'NEXT' / 'BACK' button to return to the testing mode.
- 5.4.6.3 When automatic mode is selected list of SOP's is displayed. Select the SOP by turning the knob and then confirm by pressing the knob
- 5.4.6.4 First step of the SOP is displayed. Press the knob to activate the pump
- 5.4.6.5 Press 'NEXT' / 'BACK' for moving to next step. The pump can be opened and closed at any time except when the pump head is rotating
- 5.4.6.6 The end of the step is reached when the last sequence of the SOP is completed. Press 'NEXT' / 'BACK'. The pump head opens and testing procedure screen is displayed
- 5.4.6.7 The rotation speed of the pump can be increased or decreased while the pump is running by turning the knob option for changing speed appears



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on the screen confirm on 'YES' option and then change the speed by rotating the knob.

5.5 General procedure for sterility is as follows:

- 5.5.1 Install the desired type of cannister to the Steritest Equinox Pump following step 5.4.5.1 to 5.4.5.4.
- 5.5.2 Remove cap of needle and prick the needle of the cannister tubing into the rubber stopper of bottle containing peptone water. Close the pump head, set the rotation speed at 50, close the pump head and press the knob or footswitch to start the p
- 5.5.3 Invert the bottle and hang it on the bottle holder. Transfer 100 ml of peptone water to the cannisters (50 ml each), apply the red caps and let the peptone water to filter through the cannisters for prewetting of the filters. Stop the pump by pressing the knob or footswitch
- 5.5.4 Remove the red caps and prick the needle to the bottle containing sample. Start the pump and invert the sample bottle. Transfer the sample to the cannisters and apply red caps to allow the filtration of the sample
- 5.5.5 Rinse the filter with required amount of peptone water as per sample requirement
- 5.5.6 Apply yellow caps to the bottom of the cannisters, set the rotation speed to 50 and transfer Soybean casein digest broth to one of the cannister by blocking the tubing of other cannister.
- 5.5.7 Similarly transfer Fluid thioglycollate medium to the other cannister at rotation speed of 25.
- 5.5.8 Close the tubing of both the cannister by closing the valves provided above the cannisters and cut the tubing after the valves with sterile scissors leaving appropriate length above the cannister to fix the open end of the tubes on the knob provided over the vent filter of the respective cannister.
- 5.5.9 Refer operator's manual for trouble shooting
- 5.5.10 Remove power cord after switching off power supply
- 5.5.11 After the test is over press 'ON' / 'OFF' button to shutdown the system. The equipment will be in standby mode and the LCD will be switched off.



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6.0 Forms and Records

Nil

7.0 Reference

- 7.1 Sop “Standard operating and cleaning procedure of Dynamic Pass Box”.
- 7.2 Sop “Entry and exit in Aseptic area of Microbiology Laboratory”.
- 7.3 Sop “Standard operating, monitoring and cleaning procedure of Isolator”.
- 7.4 Sop “Environmental monitoring in Microbiology Section”.
- 7.5 Sop “Disposal of used Microbial media, cultures and contaminated materials”.
- 7.6 Sop “Cleaning, Sanitization and Disinfection in Microbiology laboratory”.

8.0 Distribution

- 8.1 Master Copy : Documentation Cell (Quality Assurance)
- 8.2 Controlled Copies : Production, Quality Control, Engineering, Stores, Q.A

9.0 History

Date	Revision Number	Reason for Revision