



**STANDARD OPERATING PROCEDURE**

**Department:** Engineering

**Title:** Procedure for Integrity Testing & Replacement of Vent Filter of Water System

<b>SOP No.</b>		<b>Revision No.</b>	
<b>Effective Date</b>		<b>Supersedes No.</b>	
<b>Review Date</b>		<b>Page No.</b>	1 of 6

**1.0 OBJECTIVE:**

To lay down a Procedure for Integrity Testing & Replacement of Vent Filter of water system.

**2.0 SCOPE:**

This SOP is applicable for Integrity Testing & Replacement of Vent Filter of water system at .....

**3.0 RESPONSIBILITY:**

Officer / Executive – Engineering

**4.0 ACCOUNTABILITY:**

Head – Engineering

**5.0 DEFINITIONS:**

Not Applicable

**6.0 PROCEDURE:**

- 6.1 Open the housing and remove the Vent Filter. Check physical condition of the filter and the gaskets. If OK, Assembled the Vent filter in test housing.
- 6.2 Prior to conduct Bubble Point Test of the Vent Filter it is to be assembled in Test housing and the Vent Filter must be completely wetted with Water for Injection at Room Temperature.
- 6.3 Close the inlet valve of Filter housing.
- 6.4 Attach the air line in the inlet of Instrument and outlet of instrument to the air inlet of Filter housing
- 6.5 Connect with flexible tube fitting and dip the tube in containing WFI.
- 6.6 Connect the filtered air pressure to the release valve of housing.
- 6.7 Slowly open the air supply, pressure is achieved at 1320-5000 mbar and stabilization for two minutes.



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- 6.8 If no continuous stream of bubbles comes out from the cartridge outlet in water for injection the filter passes the test.
- 6.9 Disconnect the air supply and open the release valve to release the pressure in housing, close the release valve.
- 6.10 Record the filter integrity test data in “**Vent Filter Integrity Test Record**” as per format shown in **Annexure-I**.
- 6.11 Number of recommended integrity cycles of vent filters is presented in **Annexure-III**.

**Vent filter integrity test frequency:** Every three month  $\pm$  7 days or as and when required.

**6.11.1 Filter replacement:**

- 6.11.1.1 Filter shall be replaced after completion of number of integrity cycles or at the frequency of one year  $\pm$  1 month whichever is earlier.
- 6.11.1.2 If vent filter does not passes filter integrity test discard the filter, install new vent filter and check its integrity. Investigation shall be done through QMS tool to identify any significant impact on product quality, system & other functions due to failure of integrity.
- 6.11.1.3 Before replacement of vent filter its integrity shall be performed.
- 6.11.1.4 Filter replacement record shall be maintained in Annexure-II.

**7.0 ABBREVIATIONS:**

SOP	Standard Operating Procedure
WFI	Water for Injection
Ltd.	Limited
No.	Number

**8.0 ANNEXURE:**

<b>ANNEXURE No.</b>	<b>TITLE OF ANNEXURE</b>	<b>FORMAT No.</b>
Annexure-I	Vent Filter Integrity Test Record	
Annexure-II	Vent filter replacement record	
Annexure-III	Recommended Integrity Cycles of Vent Filters	



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**9.0 DISTRIBUTION:**

Master Copy  
Controlled Copy No.1

Quality Assurance Department  
Engineering Department

**10.0 REFERENCES:**

In-House

**11.0 REVISION HISTORY:**

<b>Revision No.</b>	<b>Change Control No.</b>	<b>Details of Changes</b>	<b>Reason of Changes</b>	<b>Effective Date</b>	<b>Done By</b>
00	Not Applicable	Not Applicable	New SOP		







**PHARMA DEVILS**  
ENGINEERING DEPARTMENT

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**ANNEXURE – III**  
**RECOMMENDED INTEGRITY CYCLES OF VENT FILTERS**

**EFFECTIVE DATE:**

**REVISION No.:**

<b>Filter Make</b>	<b>Filter Catalogue No.</b>	<b>Filter Pore Size</b>	<b>No. of Recommended Integrity cycles</b>

**Prepared by:**  
**Engineering**  
**Sign & Date**

**Checked by:**  
**Department Head**  
**Sign & Date**

**Approved by:**  
**Head-QA**  
**Sign & Date**