



Title: Integrity Testing, Handling, Replacement of Vent Filters

SOP No.:		Revision No.:	00
Effective Date:		Supersedes No.	Nil
Review Date:		Page No.	1 of 8

1.0 OBJECTIVE:

To lay down a procedure for Filter Integrity Testing, Handling and Replacement of Vent Filters and replacement of capsule filter.

2.0 SCOPE:

This SOP is applicable for filter integrity testing, handling and replacement of vent filters of PWG & WFI generation tank and replacement of capsule filter of MCDP plant and PSG plant.

3.0 RESPONSIBILITY:

Officer / Executive – Engineering

4.0 ACCOUNTABILITY:

Head – Engineering

5.0 ABBREVIATIONS:

ER	Engineering
Ltd.	Limited
No.	Number
Pvt.	Private
MCDP	Multi Column Distillation Plant
PSG	Pure Steam Generator
QA	Quality Assurance
SOP	Standard Operating Procedure
NMT	Not More Than

6.0 PROCEDURE:

- 6.1 Ensure the respective system shall be in Standby / off condition.
- 6.2 Always wear sterile hand gloves before touching the filter.
- 6.3 Open the end connection and remove the filter housing from the respective tank.
- 6.4 Covered the end connection of vent filter housing of tank with aluminum foil.
- 6.5 Now open the vent filter housing and remove the filter carefully.
- 6.6 Cover the removed filter with Aluminum foil and put the filter in clean polythene bag and fix the status label “FOR INTEGRITY PURPOSE”.
- 6.7 Handle the removed filter carefully to avoid any possible damage/extraneous contamination.
- 6.8 Removed vent filter shall be sending for Integrity test purpose when required.
- 6.9 Integrity of vent filter shall be carried out in house with their respective SOP, of concern department.



Title: Integrity Testing, Handling, Replacement of Vent Filters

SOP No.:		Revision No.:	00
Effective Date:		Supersedes No.	Nil
Review Date:		Page No.	2 of 8

- 6.10** After completion of Integrity Test, filter shall be received with the respective test report results.
- 6.11** Based on the report of removed vent filter integrity, vent filter will be used next time if it pass the integrity test and if it fail then destroy the filter and new integrity pass (received from vendor) vent filter shall be used and same shall be mention in **Annexure-IV** “ Vent filter destruction record”.
- 6.12** Remove the aluminum foil from end connection of vent filter housing.
- 6.13** Clean the filter housing and its clamp with lint free cloth & fix the vent filter housing with integrity pass filter.
- 6.14** Start the respective system in operation
- 6.15** Whenever any activity performed on vent filter i.e. Vent filter removal for integrity test, Vent filter replacement as per frequency or any damaged condition then sanitize the respective system as per SOP after carrying out vent filter activity.
- 6.16** Integrity of the Vent Filter shall be checked after usage of Quarterly ± 7 Day and shall be carried out before sanitization.
- 6.17** Records shall be maintained as per the **Annexure – I** and affix the status label as per **Annexure – II**.
- 6.18** Result of Integrity shall be attached with the **Annexure – I**.
- 6.19** Replacement of Vent filter shall be done after one year usage ± 30 Days & whenever required and shall be recorded as per **Annexure-I**.

Note: Check the vent filter physically for any damage before every sanitization

- 6.20** Replacement of capsule filter is carried out with a frequency of yearly ± 30 days.
- 6.21** Status label of vent filter and capsule filter replacement shall be affix on equipment as per **Annexure-V** titled as “Status Label of Filter Replacement”.

7.0 REFERENCES:
Not Applicable



Title: Integrity Testing, Handling, Replacement of Vent Filters

SOP No.:		Revision No.:	00
Effective Date:		Supersedes No.	Nil
Review Date:		Page No.	3 of 8

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Filter Integrity Testing Record of Vent Filters	
Annexure-II	Status label	
Annexure-III	Filter Replacement Record	
Annexure-IV	Filter Destruction Record	
Annexure – V	Status Label of Filter Replacement	

ENCLOSURES: SOP Training Record.

9.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Engineering
- Master Copy Quality Assurance

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



PHARMA DEVILS

ENGINEERING DEPARTMENT

Title: Integrity Testing, Handling, Replacement of Vent Filters

SOP No.:		Revision No.:	00
Effective Date:		Supersedes No.	Nil
Review Date:		Page No.	5 of 8

ANNEXURE – II

STATUS LABEL
FILTER ID:
FILTER PORE SIZE:
INTEGRITY DONE ON:
INTEGRITY NEXT DUE ON:
REMARKS:
CHECKED BY : (SIGN & DATE)



PHARMA DEVILS

ENGINEERING DEPARTMENT

Title: Integrity Testing, Handling, Replacement of Vent Filters

SOP No.:		Revision No.:	00
Effective Date:		Supersedes No.	Nil
Review Date:		Page No.	6 of 8

ANNEXURE-III FILTER REPLACEMENT RECORD

LOCATION:

S.No.	Filter ID. No.	Done on Date	Due on Date	Done By Sign & Date	Reviewed By Sign & Date	Remarks if any



PHARMA DEVILS

ENGINEERING DEPARTMENT

Title: Integrity Testing, Handling, Replacement of Vent Filters

SOP No.:		Revision No.:	00
Effective Date:		Supersedes No.	Nil
Review Date:		Page No.	7 of 8

ANNEXURE-IV FILTER DISTRUCTION RECORD

LOCATION:

S.No.	Filter No.	Reason for Discard	Destruction Date	Done by Sign & date	Review by Sign & date	Remarks if any



PHARMA DEVILS

ENGINEERING DEPARTMENT

Title: Integrity Testing, Handling, Replacement of Vent Filters

SOP No.:		Revision No.:	00
Effective Date:		Supersedes No.	Nil
Review Date:		Page No.	8 of 8

ANNEXURE – V

STATUS LABEL OF FILTER REPLACEMENT
FILTER ID:
FILTER PORE SIZE:
Replacement Done On:
Replacement Due On:
REMARKS:
CHECKED BY : (SIGN & DATE)