



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Procedure for Issuance, Cleaning, Replacement & Destruction of Vent & Air Filter	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a Procedure for Issuance, Cleaning, Replacement & Destruction of Vent filter & Air filter used in Ointment Section.

2.0 SCOPE:

This SOP is applicable for Issuance, Cleaning, replacement & Destruction of Vent filter & Air filter used in Ointment Section.

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

IPA	Isopropyl Alcohol
Ltd.	Limited
MOC	Material of Construction
PO	Production Ointment
Pvt.	Private
No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 PRECAUTIONS:

6.1.1 Handle the Filter carefully to avoid any possible damage / extraneous contamination.

6.1.2 Never remove the filters from line when it is in under operation.

6.1.3 Filter should be clean with their respective cleaning agent.

6.2 ISSUANCE & USAGE OF FILTERS:

6.2.1 Receive Filter and checked that these are received as per purchase order.

6.2.2 Check the Certificate of Analysis from manufacturer. Verify that COA is as per requirement out inspection of Filter for the following parameters:

a. Pore size

b. Material of Construction (MOC)



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6.2.3 Record the issuance of filter as per **Annexure – I**.

6.2.4 Issued filter shall be placed in their respective filter housing assembly.

6.2.5 After every change over or before starting of next batch/product, vent/air filter shall be remove from the housing and shall be visually inspected to ensure any physical damage.

6.2.6 If any physical damage observed in the filter, then it will be replaced with new filter.

6.2.7 Visual inspection observation of the filter shall be recorded in the **Annexure-II**, for satisfactory observation shall be recorded as “*satisfactory*” in respective column and for any abnormality/damage shall be recorded as “*Not satisfactory*”.

6.3 CLEANING OF VENT/ AIR FILTERS:

6.3.1 Remove the filter from manufacturing plant and transfer to washing area for cleaning and cover filter housing with Aluminum foil to avoid contamination.

6.3.2 For cleaning of Vent/Air filter, dip the filter in 70% IPA for 20 minute.

6.3.3 After that dry it by flushing with filtrated compressed Air.

6.3.4 Record the cleaning of filter as per **Annexure – II**.

Frequency: monthly ± 3 working days

6.4 DESTRUCTION OF FILTERS:

6.4.1 Officer/Executive Production shall send the rejected filters to the Engineering Department for destruction.

6.4.2 Record the Destruction of filter as per **Annexure – I**.

6.5 REPLACEMENT OF FILTERS:

6.5.1 Once in a year.

6.5.2 If damaged physically it will be replaced by already checked filter.

6.5.3 Record the Replacement of filter as per **Annexure – I**.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Filter issuance, Replacement and Destruction Record	
Annexure-I	Filter Cleaning and Visual Inspection Record	

ENCLOSURES: SOP Training Record



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8.0 DISTRIBUTION:

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

9.0 REFERENCES:

Not applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



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ANNEXURE – II FILTER CLEANING AND VISUAL INSPECTION RECORD

Date	Filter Serial No.	Cleaning		Done By	*Visual inspection (For any physical damage)	Checked By Production	Verified By QA	Remarks
		From	To		Satisfactory/ Not satisfactory			

*Visual inspection shall be performed before starting of every Batch/ Product