PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Operation and Cleaning of Reverse Laminar Air Flow	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

OBJECTIVE:

To lay down a procedure to describe the steps to be followed for the operation of Reverse Laminar Air Flow, while sampling the raw material.

SCOPE:

This SOP is applicable to sampling of all the raw materials required for production, performed using following reverse laminar air flow.

1. Klenzaids RM Sampling room
2. Klenzaids RM Sampling room

RESPONSIBILITY:

Technical supervisor & Section In-charge.

ACCOUNTABILITY:

QC Head.

REFERENCES:

In- House.

ATTCHMENT:

Attachment – I Laminar Monitoring Record, Form
Attachment – II Reverse Laminar Air flow bench cleaning record

PROCEDURE:

1.0 Operation Of Reverse Laminar Air Flow Cabinet:

1.1 At the start of day ensure the cleanliness of the Reverse Laminar Air Flow 30 min. prior to commencement of the sampling and weighing operation and check the filter cleaning tag of Reverse Laminar Air Flow affixed by engineering department for cleaning status.

1.2 Switch ‘ON’ the main power supply.

1.3 The pressure differential reading must be observed and recorded at the beginning and end of shifts in Monitoring Record. It should range between 5 and 15 mm.

1.4 Clean the Reverse Laminar Air Flow after completion of the sampling operation and in-between the sampling of two materials.

1.5 Switch 'OFF' the power supply of the Reverse Laminar Air Flow and that of the tube lights after the completion of sampling operation.

1.6 Switch 'OFF' the main power supply.

Note : a) When gauge reading increases above 15 mm or the pressure decreases below 5 mm inform the engineering department and get it rectified.

b) Suspend the usage of laminar air flow until it is rectified.

2.0 Cleaning Of Reverse Laminar Air Flow Cabinet

2.1 Batch Change over

2.1.1 Collect all the spilled materials using a vacuum cleaner.

2.1.2 Wipe external surface of the table and balance with a lint-free mopping pad.

2.2 Product Change over

2.2.1 Remove containers from the cabinet.

2.2.2 Collect all the spilled materials using a vacuum cleaner.

2.2.3 Wipe the external surface of the table and balance with a lint-free mopping pad soaked in 2.5 % Dettol solution.

2.2.4 Clean the surface with 70 % IPA using a lint-free cloth.

2.2.5 Wipe the walls of the Reverse laminar air flow cabinet with 70 % IPA using a lint-free cloth.

Note :

1. At the end of the shift remove the top cover of the sampling table, clean the inside chambers for remnants of the materials sampled using the vacuum cleaner.
2. Record the details of the cleaning in "Reverse Laminar Air flow bench cleaning record".

3.0 ABBREVIATIONS:

CC No. : Change control number

SOP : Standard operating procedure

QC : Quality control

QA : Quality assurance

IPA : Iso Propyl alcohol

ATTACHMENT I
Δ P MONITORING RECORD

Instrument: Magnehelic gauge of Reverse Laminar Flow

Location: Raw material sampling area **Month & Year:**

Date	Δ P Laminar No.1		Δ P Laminar No.2		Sign.	Remark
	Beginning of shift	End of shift	Beginning of shift	End of shift		

ATTACHMENT II

Reverse Laminar Air Flow Bench Cleaning Record

Area: ______________________________________ **Month :** ______________________________

Booth I.D.No. : ____________________________

Date	Material	AR No.	Activity	Time		Done By	Checked By	Remarks
				From	To			