



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

### STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Control	<b>SOP No.:</b>
<b>Title:</b> Operation and Cleaning of Sampling Booth	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

#### 1.0 OBJECTIVE:

To lay down a procedure for operation and cleaning of sampling booth.

#### 2.0 SCOPE:

This SOP shall be applicable for sampling booths installed in Raw material and Packaging Material store.

#### 3.0 RESPONSIBILITY - Execution- Executive QC Checking -Assistant Manager QC

#### 4.0 ACCOUNTABILITY – Manager Quality Control

#### 5.0 PROCEDURE:

5.1 Switch 'ON' the mains.

5.2 Switch 'ON' the light.

5.3 Start blower at slow speed at least 15 minutes before the sampling.

5.4 Note the reading of differential pressure daily in Annexure-I

5.5 Always open the material for sampling when system is 'ON'

5.6 Sample the Raw material as per Current version of SOP and Packaging material as per current version of SOP.

5.7 In case of raw material, don't take sampling device outside of booth, but collect in closed container in booth itself to avoid any contamination outside the booth.

5.8 Use clean sampling device for different material.

5.9 Close the poly bag/ containers of sampled material under laminar flow unit, before taking it out.

5.10 Put 'OFF' the system after use.

#### 5.11 Precautions

5.11.1 It is important and most essential to avoid any air borne contamination in the material during sampling.

5.11.2 Core filter and 5 micron filter are cleanable and required to clean it periodically as and when required.

5.11.2 The recommended Magnehelic gauge is between 7 to 15 mm of water.



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5.11.3 If reading goes more than 15, it indicates chocking of HEPA filter and needs replacement of HEPA filter.

5.11.4 Whenever replacement of HEPA filter takes place, the integrity of the filter should be verified by DOP test.

5.11.5 If reading goes down, it indicates chocking of pre-filter which requires cleaning. Inform engineering department for cleaning of pre-filter.

#### 6.0 SAFETY & PRECAUTIONS:

Not Applicable

#### 7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date

#### 8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

#### 9.0 REFERENCES:

Sampling & verification of PM.

Sampling procedure for RM.

#### 10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure



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No. : Number

QC : Quality Control

HEPA : High efficiency particulate air

PSIG : Pound per square inch gauze

DOP : Dioctyl phthalate

**ANNEXURE I:** Record of Sampling Booth Magnehelic gauge Reading

