INSTALLATION QUALIFICATION

PROTOCOL CUM REPORT

FOR

DUST-EXTRACTOR

EQUIPMENT ID. No.	
LOCATION	**Compression**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DUST-EXTRACTOR	PROTOCOL No.:

CONTENTS

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DUST-EXTRACTOR	PROTOCOL No.:

1.0 PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Dust Extractor.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Dust Extractor** to be installed in the Compression.
- The Dust Extractor is a standalone unit with plug in type electrical connections for operation and is on castor wheels. Hence, may be moved as per requirement to other area of operation which shall not change the performance of equipment.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Dust Extractor.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation, Authorization, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity.
Production	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Dust Extractor Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Dust Extractor
Equipment	
Manufacturer's Name	Fluid Pack
Model	
Sr. No.	
Supplier's Name	Fluid Pack
Location of Installation	Compression

6.0 SYSTEM DESCRIPTION:

Variable Air Flow (CFM):

It allows adjusting the amount of air flow and it is typically measured in CFM. Higher the CFM more air is being moved and the more suction is being created.

Filter Bags:

It is for containing dust. They make removal and transferring debris, easy and clean. Filter bag with cap seals prevent the dust to spread within the machine while transporting.

Filter Cleaner:

Filter cleaner remove the accumulation of dust and debris from the internal filter, reducing the chance of overheating the motor and electrical components when there is poor air circulation. It provides thermal protection for motor as an added level of safety.

Venting and Exhaust:

Extract the material by creating vacuum, pulling it forcefully toward the filter bag resulting in collection of dust in filter bag and left over air is being removed out.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P & ID).
- Electrical Circuits Diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction of components.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 General Checks and Location Suitability:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly grind without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Compression		
Room Condition	General working condition.		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.2 Equipment Verification:

Installation Checks	Acceptance Criteria		Observation	Observed By (Engineering) Sign/Date
Equipment	Dust Extractor			
Capacity	150 CFM			
ELECTRICAL INSTALLATION:				
Electricity	Voltage	415 V		
	Phases	3 Phase		
	Frequency	50 Hz		
Electrical connections have been provided and secured.	Should be provided & secured.			
All components in the panel are properly secured.	Should be properly secured.			
All terminals are tightened	Should be tightened.			
Earthing connection to control panel & equipment.	Earthing connection to control panel & equipment should be provided.			

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DUST-EXTRACTOR	PROTOCOL No.:

8.3 Installation Checks:

S.No.	Specification	Observation	Observed By (Engineering) Sign/Date
1.	Check the proper mechanical installation of Dust Extractor.		
2.	Check the proper electrical installation of Dust Extractor.		
3.	Check the parts are working properly.		
4.	Check the equipment is free from any defects.		
5.	Check the finishing of product contact parts.		
6.	Check that all parts are getting lubricated.		
7.	Check that Shaking Handle fitted properly and works properly.		
8.	Check that Cotton Bags fitted properly.		
9.	Check that Dust Collection Bins correctly mounted and put at the correct place.		
10.	Check that Suction Blower dully balanced.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.4 MOC Verification List:

S.No.	Component	MOC	Observation	Observed by (Engineering) Sign/Date
1.	Main Body	SS 304		
2.	Dust Collection Tray	SS 316		
3.	Suction Nozzle	SS 316		
4.	Blower	SS Fabricated		
5.	Dust Collection Bag	Cotton		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Sign/Date: ……

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DUST-EXTRACTOR	PROTOCOL No.:

8.5 Equipment Verification:

S.No.	Name of The Component	Technical Specification	Observation	Observed By (Engineering) Sign/Date
1.	Equipment Name	"Accura'' dust extractor unit		
2.	Model	……		
3.	Overall Dimension	Length : 660 mm Width : 470 mm Height : 745 mm		
4.	Net Weight	80 Kg		
5.	Gross Weight	100 Kg		
6.	Electrical Motor	Make : MEGHA ROTOTECH RPM : 2830 Voltage : 415 V HP : 1 HP PHASE : 3 Phase Frequency : 50 Hz		
7.	Suction Capacity	150 CFM		
8.	Inlet Connection	Quantity : 4 Nos. Dia. : 1 ½ " (38.1)		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.6 Safety:

Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Well embedded equipment	For proper sifting		
Electrical wiring and earthing.	Electrical wiring should be as per approved drawings. Double external earthing to control machine (panel and motors).		
Guard	Should be provided For Motor safety.		
Start On/Off switch: To stop the process immediately.	Should be provided For equipment and operator safety.		
MCB for electrical overload	Should be properly installed.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 REFERENCES:

The Principle Reference is the following:

- Master Validation Plan
- Schedule-M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

The following references are used to give addition guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition/March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, Beta. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Calibration certificates.
- Operation and Maintenance Manual.

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

Sr.	:	Senior
No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
cGEP	:	Current Good Engineering Practices
EU	:	European Union
IQ	:	Installation Qualification
Amp.	:	Ampere
MOC	:	Material of Construction
NLT	:	Not Less Than
HP	:	Horse Power
KW	:	Kilo watt
SS	:	Stainless Steel
ID.	:	Identification
Kg	:	Kilo gram
Ltrs	:	Liters
mm	:	Millimeter
MCB	:	Miniature Circuit Break

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			