DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

DUST-EXTRACTOR

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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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)			

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DUST EXTRACTOR

2.0 OBJECTIVE:

- To prepare the Design Qualification document for Dust Extractor on basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **Dust Extractor (Make: Fluid Pack)**.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.

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 and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Post Approval of Qualification Protocol cum Report after Execution.
Engineering	• Review of the Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. ➢ GA Drawing. ➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/brochures. ➢ Details of utilities Required. ➢ Identification of components for calibration. ➢ Material of construction of Product Contact Parts. ➢ Brief Process Description. ➢ Safety Features and Alarms. • Review of Qualification Protocol after Execution.

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5.0 BRIEF EQUIPMENT 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.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification. The manufacturer of equipment ensures complies with User Requirement Specification.

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7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: The Dust Extractor shall be able for extracting of extra material during compression process.	The Dust Extractor should be able to extract the extra material through vacuum during the Compression process.	Process Requirement
Working: Working of Dust Extractor	Dust Extractor works through vacuum suction by extracting extra material to prevent inter-mixing of material.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Phase : 3 Phase Volt : 415 Volt Hz : 50 Hz	cGMP Requirement
Room Condition	Temp : 22±2 °C RH : 50±5 %	Process Requirement

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7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S. No.	Name of The Component	Technical Specification
1.	Equipment Name	''ACCURA'' DUST EXTRACTOR UNIT 150 CFM
2.	Model	ACRA-DE-150
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)

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Machine Parts	Acceptance Criteria
1.	Main Body	SS 304
2.	Dust Collection Tray	SS 316
3.	Suction Nozzle	SS 316
4.	Blower	SS Fabricated
5.	Dust Collection Bags	Cotton

7.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.	Safety Requirement
Joints	Welding of joints without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grind without any sharp edges.	Safety Requirement
Leveling and Balancing	Equipment should be properly balanced & leveled.	Safety Requirement
Electrical Wiring and earthing	Electrical wiring should be as per approved drawings. Single external earthing to control machine (panel and motors) and operator should be provided.	Safety Requirement
Noise Level	Below 80 db	GMP & Safety Requirement

7.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Dust Extractor	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment).	Process Requirement

Reference: (1) User Requirement Specifications (URS).

(2) Design & Functional Specifications provided by Vendor.

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8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents.

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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

URS	:	User Requirement Specification
cGMP	:	Current Good Manufacturing Practice
cGEP	:	Current Good Engineering Practice
PO	:	Purchase Order
Kg	:	Kilogram
mm	:	Millimeter
SS	:	Stainless Steel
OD	:	Oral Solid Dosage
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature Circuit Breaker
DQ	:	Design Qualification
db	:	Decibel
RH	:	Relative Humidity
RPM	:	Revolution per Minute
HP	:	Horse Power
AMP	:	Ampere
STD	:	Standard

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			