

QUALITY ASSURANCE DEPARTMENT

# DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DUST COLLECTOR

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DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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# DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DUST COLLECTOR

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# 1.0 PROTOCOL PRE – APPROVAL:

#### PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

# **REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

# **APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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### **2.0 OBJECTIVE:**

- To carry out the Design Qualification of Dust Collector used in Compression.
- To prepare the Design Qualification document for Dust Collector on basis of specifications this is taken by the approved 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 Collector.
- The equipment shall be operated as per the cGMP requirements.



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#### 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	
	Preparation & Review of the Protocol cum Report.	
	Assist in the verification of Critical Process Parameters, Drawings as per	
	the Specification.	
<b>Quality Assurance</b>	Review of Qualification Protocol cum Report after Execution.	
	Co-ordination with Production and Engineering to carryout Design	
	Qualification.	
	Monitoring of Design Qualification Activity.	
	Review of the Protocol cum Report.	
Production	Assist in the verification of Critical Process Parameters, Drawings as per	
Production	the Specification.	
	Review of Qualification Protocol cum Report after Execution.	
	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	
Engineering	> Specification of the sub-components/ bought out items, their Make,	
Engineering	Model, Quantity and backup records / brochures.	
	Details of utilities	
	<ul> <li>Identification of components for calibration</li> </ul>	
	Material of construction of all components	
	Brief Process Description	
	> Safety Features and Alarms	
	Review of Qualification Protocol cum Report after Execution.	



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### **5.0 PROJECT REQUIREMENTS:**

To confirm the safe delivery of the equipment from the supplier Site. To ensure that no unauthorized and/or unrecorded design modification shall take place.

If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented. The purpose of machine shall be used to dust free area.

#### **6.0 BRIEF PROCESS DESCRIPTION:**

Capture the dust with proper capture velocity from process area and send the dust collector chamber with the help of trapping Canvas Cotton Bag Filter simultaneously dust free air will go by 10 micron filter and then send to the environment.

Bag filter dust collector is efficient pollution control equipment and filtration is carried out through woven or non-woven filter media in form of bags. The cleaning action is due to high pressure air passed in the reverse direction or by providing vibration to the bags through the vibratory motor which generates the shocks to dislodge the dust particles from the bags.

S.No.	Parameter	Description
1.	<b>Dust Collector Details</b>	It comprises of:
		Hose PVC Pipe for connecting with the process equipments
		HDPE Pipe for connecting with the Equipment
		Butter Fly Valve
		AC Induction Motor
		Canvas Cotton make Filter Bag
		Reverse Rotating Fan
		Electrical Starter Panel
2.	<b>Environmental conditions:</b>	
<b>2.</b>	Temperature	Ambient (up to 30°C)
3.	Quantity of Air Suction	Air Suction Velocity: 400 FPM

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# 7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User requirement Specifications.

#### 8.0 CRITICAL VARIABLES TO BE MET:

#### **8.1 PROCESS / PRODUCT PARAMETERS:**

Critical Variables	Acceptance Criteria	Reference
<b>Application:</b> For collecting or receiving	During collecting the dust from	Process Requirement
dust from various process equipment like	sifter, it should not be release in the	
Vibro Sifter.	process area.	
Working:	To maintain the cleanliness level	Process Requirement
Working of Dust Collector	during manufacturing.	
Electrical Control Panel	The system should have Electrical	Design Requirement
	Control Switch.	

# **8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:**

Critical Variables	Acceptance Criteria	Reference	
Utility connections s	hould be available as per the manufacturer's specification.		
<b>Electrical Supply</b>	• Voltage: 230 V (1 Phase) / 415 V Limit +/- 10 % (3 Phase) cGMP Requirement		
	• Phases: 1 Phase & 3 phase		
	• Frequency: 50 Hz (+ /- 3 %)		
<b>Area Condition</b>	Area Condition Should be able to meet the requirement as per given by the		
	manufacturer		

# **8.3** TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	Parameters	Acceptance criteria	
1.	Body	Over All Dimension in mm : 1700 x 600 x 600 MM	
		MOC : MS painted sheet	
2.	Accessories	<b>Body :</b> Made up of MS painted sheets	
		AC Induction Motor: Qty.: 01 No.	
		Reverse Rotating FAN: Qty.: 01 No.	
		Butter Fly Valve at Dust Extraction Pipe: Qty.: 01 No.	
		Control Panel for START / STOP: Qty.: 01 No.	
		Canvas Cotton Filter Bag for Trapping the Dust: Qty.: 05 No.	
3.	AC Induction	Make: - "Crompton"	

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S.No.	Parameters	Acceptance criteria
	Motor	<b>H.P</b> : – 3.0 H.P.
		<b>RPM</b> : - 2830
		<b>Volt</b> : - 415±10%
		AMP: -5.03A
		Frame: - NA
		S. No.: – NTDF32

#### **8.4 MATERIAL OF CONSTRUCTION:**

S.No.	Parts Name	Material of Construction
1.	Dust Collector Body	MS painted sheet
2.	Base & stand	SS 304
3.	Contact Part	SS 316

#### **8.5 SAFETY:**

S.No.	Parameters	Safety / cGMP	Reference
1.	Triclover Clamp should be provided on Dust Extraction Pipe	Triclover Clamp should be provided on Dust Extraction Pipe so that entire pipe can be cleaned.	cGMP Requirement
2.	Butter Fly valve should be provided at Dust Extraction Pipe.	Butter Fly should be given for maintaining the air velocity in the pipe.	cGMP Requirement

#### **8.6 VENDOR SELECTION:**

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

Verified By Sign & Date



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9	DOCUMENTS TO BE ATTACHED:		
	• Any other relevant documents.		
10	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):		
11	ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:		
10	DECOMMENDATION.		
12	RECOMMENDATION:		



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#### **13 ABBREVIATIONS:**

URS : User Requirement Specification

cGMP : Current Good Manufacturing Practice

Pvt. : Privet

Ltd : Limited

GB : General Block

mm : Millimeter

DQ : Design Qualification

RPM : Revolution Per Minute

HP : Horse Power

AMP : Ampere

STD : Standard



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# 14 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			