DESIGN QUALIFICATION PROTCOL CUM REPORT FOR POWDER TRANSFER SYSTEM

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR POWDER TRANSFER SYSTEM	PROTOCOL No.:

APPROVALS – VENDOR……...

Action	Designation	Name	Date	Signature
Prepared by				
Approved by				

APPROVALS – CLIENT: M/s. …….

Action	Department	Name	Date	Signature
Approved by	Engineering			
Approved by	Production			
Approved by	Quality Assurance			

REVISION HISTORY:

Revisions	Date	Amendments	Remarks

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR POWDER TRANSFER SYSTEM	PROTOCOL No.:

TABLE OF CONTENTS

1.0 ACRONYMS AND ABBREVIATIONS:

Acronym	Description
GA	General Assembly
CL	Component List
IL	Instrument List
VTOP	Validation Turn Over Package
DQ	Design Qualification
cGMP	Current Good Manufacturing Practices
ISO	International Organization for Standardization
GMP	Good Manufacturing Practices
MOC	Material Of Construction
PO	Purchase Order
SS	Stainless Steel
OS	Offer Specification
URS	User Requirements Specification
UL	Utility List
FDS	Functional design specification
VTS	Vacuum transfer system

2.0 INTRODUCTION:

The purpose of this Design Qualification (DQ) is to provide documented evidence to demonstrate that the design and documentation for the equipment meets the client's requirements and design intentions of Product, Process, Safety, Regulatory bodies and GMP obligations. This Document is referenced in the client's PO.

3.0 PURPOSE:

The purpose of this Design Qualification (DQ) aims at detailing the specifications defined and agreed between …….. and M/s. …….. for supply of the **Powder Transfer System.**

4.0 SCOPE:

This Design Qualification (DQ) is applicable to the …….., being manufactured for M/s. …….. as per their Purchase Order no: …….. dated: ……. received.

M/s. ……. reference no. for this equipment is ……...

5.0 OBJECTIVE:

The design qualification has been prepared to detail the functional specifications of the equipment and to demonstrate compliance of the equipment to the user requirement specifications and regulatory requirement.

6.0 EQUIPMENT SPECIFICATION:

CLIENT	
PURCHASE ORDER No. & DATE	
EQUIPMENT	POWDER TRANSFER SYSTEM
MODEL	
TOTAL LOAD	7.5 KW/10 HP

7.0 DESIGN QUALIFICATION TESTS & THEIR OBJECTIVES:

7.1 Documentation Verification

To ensure that all the relevant design & Project documentation is in place and referenced.

7.2 Design Verification

To ensure that the system design conforms to the Purchase Order (PO) and FDS.

7.3 cGMP Requirement Verification

To ensure that cGMP & GAMP requirements are incorporated into the system design.

7.4 Instrumentation and Controls Verification

To ensure that all Instruments and Controls identified in the Instrument List are referenced in the GA drawing.

7.5 Components Verification

To ensure that all major components identified in the Component List have been incorporated in the GA drawing.

7.6 Utilities Verification

To ensure that all utilities as identified in the Project document, and referenced at Site identified in the Utility List & incorporated in the GA drawing.

7.7 Safety Verification

To ensure that the equipment is safe for the Operators and the working environment.

8.0 CONSTRUCTIONAL DESCRIPTION:

The proposed system is a Vacuum Transfer System in the lean phased Vacuum conveying mode, which achieves material transfer by introducing the material into the moving stream of air at desired rate. Conveying is achieved automatically and continues till the material reaches its final destination.

The major components of the Vacuum transfer system are:

- **Vacuum Pump**
- **Vacuum Transfer System**
- **Vacuum Supporting Device**
- **PU Cloth**
- **Silencers**
- **Non Return Valve**
- **Suction Air Filter**
- **Safety Valve**
- **Measuring and Monitoring Device**
- **Electrical Actuated Solenoid Valve**

7.1 Vacuum Pump

To create negative suction in the system to transfer the material.

7.2 Vacuum Transfer System

To separate the air from the material and intermittently discharge the material.

7.3 Vacuum Supporting Device

To support the cyclone separator on its swivelling arm. The cyclone separator can be positioned on / away from the discharging device by swivelling the support arm.

7.4 PU Cloth

To connect the discharge port of the vacuum transfer system to the charging port of the existing devices.

7.5 Silencers

The fitting of silencers on the suction and delivery side of the machine. These silencers should be located as near the machine. The position is which the silencers are fitted horizontally.

7.6 Non Return valve

When the machine is switched off, the non return valve disconnects the machine from the remaining compressed air system. It also prevents the machine against turning back after switch off.

7.7 Suction Air Filter

The air filter of 5 Micron safeguards the machine against dirt and dust. It also prevents the foreign material entering the working chambers. Hence the reliability and service life of the machine depends upon the efficiency of the Air Filter. Hence it is absolutely essential to run the machine with the filter.

7.8 Safety Valve

A safety valve correctly adjusted, it protects the machine against excessive increases in Vacuum. The safety valve should be mounted in such a way that it is readily accessible for control purposes.

7.9 Measuring and Monitoring Devices

Vacuum gauge supplied is quite sufficient to monitor the machine operation. It should be connected up before or after the silencer using a pressure line which should be at least 2 meters in length. The gauge itself should be mounted vibration free on the wall.

7.10 Electrical Actuated Solenoid Valve

Electrical Actuated Solenoid Valve helps in Purging of air during the process of transfer of material.

9.0 ATTACHMENTS:

DQ test sheets, detailing the objective, method and acceptance criteria for each of the above qualification tests are as attached below and must be completed.

DOCUMENTATION VERIFICATION				
Objective	Ensure that all relevant design documentation is in place and referenced.			
Method	Log the document title, reference number, and document date and revision number. Confirm that the content matches the requirement.			
Acceptance Criteria	All columns in the table below should be completed. All documents should be identified and referenced.			
Documents Expected	**Reference Number**	**Rev**	**Document Date**	**Attached Yes/No**
Purchase Order		00		
FDS		00		
GA Drawing		00		
Component list		00		
Instrument list		00		
Utility list		00		

Comments:

	Name	Signature	Date
Executed by			
Reviewed by			

DESIGN VERIFICATION	
Objective	Ensure that the System Design conforms to the Specifications in PO, FDS & GA drawing.
Method	Identify in the GA drawing as to where the requirements of Offer Specifications and/or FDS and/or PO have been reflected. Use a Yellow Highlighter to mark the drawing/s "ACCEPTED" Criteria and use a Red highlighter to mark the drawing/s "NOT ACCEPTED" criteria. Deviations, If any, should be filled out in the deviation register. Critical Dimensions and Checkpoints should be noted in the space for Comments below.
Acceptance Criteria	Ensure that all the requirements in the PO and/or Offer specifications and/or FDS and/or PO have been incorporated into the System Design (GA drawing).

Comments:

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cGMP REQUIREMENT VERIFICATION	
Objective	Ensure that the cGMP requirements have been incorporated into the System Design.
Method	Complete the table below.
Acceptance Criteria	All the cGMP requirements are incorporated into the design.

cGMP Requirement	Acceptance Criteria	Design Criteria	Pass/Fail
1) MOC	MOC of Contact Parts–SS 316 MOC of Non-Contact Parts –SS304	MOC of all the Contact parts-SS316 MOC of Non-Contact Parts –SS304	
2) Finish	Finish should be as per Pre-defined requirement.	External : 180 Grit Matt Finish Internal: 240 Grit Mirror Finish	
3) Gaskets	Suitable Gaskets should be as per pre-defined requirement. Food grade gaskets should be non-shredding, process Compatible, washable and Easily accessed.	Suitable Food Grade Silicone Gaske used for as per process requirement.	
4) Exposed Threaded Fasteners	No exposed threaded Fasteners.	Dome Bolts and nuts are to be used in all Contact area.	
5) Dust	Operation should be dust free.	Inlet/Outlet with quick clamp-able provision to connect to dust eliminating equipments.	
6) Crevices/ corners (for contact surface areas)	No crevices. Rounded corners. Smooth surfaces.	Shell, Inlet nozzle & Cone will not have any crevices; will have rounded corners and smooth surfaces.	
7) Cleaning	All Parts are easily accessible for cleaning.	All Parts can be easily accessible to dismantle for cleaning purpose.	

cGMP Requirement	Acceptance Criteria	Design Criteria	Pass/Fail
8) Sealing Arrangement	No particle to be shredded within the Body. Lubricants or coolants required for operation shall not come in contact with product.	As per G.A. Drawing No. ……., Ensure compliance that no lubricants /coolants come into product Contact. No shredding material to be used.	

Comments:

	Name	Signature	Date
Executed by			
Reviewed by			

INSTRUMENTATION AND CONTROLS VERIFICATION	
Objective	This procedure is to be executed to ensure that the instruments will perform the controls & interlock as listed in the Functional Specification identified in the instrument list & GA drawing.
Method	Review the instrument list and the functions of instruments mentioned with the GA drawing. Check their range, make and models, and ensure they are compatible to process needs, and environment, contractual agreements the details verified "ACCEPTED" Criteria with a yellow highlighter pen on the instrument list. NOT"ACCEPTANCE Criteria on the same with a red highlighter pen on the drawing. Attach thus corrected and marked instrument list labelled as 'DQ Check' to this DQ as an appendix. If any of the requirements is not mentioned in the instrument list, then the same should be mentioned in the deviation register. Then the instrument list will be revised for these corrections.
Acceptance Criteria	Instrument list should match with the FDS, Instrument List, and PO & GA drawing.

Comments:

	Name	Signature	Date
Executed by			
Reviewed by			

COMPONENTS VERIFICATION	
Objective	This procedure is to be executed to ensure that the components identified in the component list have been included in the GA drawing.
Method	Review the component list and the functions, make, range and specifications of major components with the FDS & GA drawing. Mark ACCEPTED" Criteria with a yellow highlighter pen on the component list and GA drawing. "NOT ACCEPTED" with a red highlighter pen on the drawing. Attach thus marked component list and GA drawing labelled as 'DQ Check' to this DQ as an appendix. If any of the requirements is not mentioned in the GA drawing and/or component list, then the same should be mentioned in the comments below. Then the same will be revised for the corrections.
Acceptance Criteria	Component list must match with the GA drawing and Component list.

Comments:

	Name	Signature	Date
Executed by			
Reviewed by			

UTILITIES VERIFICATION

Objective	This procedure is to be executed to ensure that all required utilities have been included in the Utility list & GA drawing.
Method	Verify that all the utilities, as appearing in the utility list should be on the GA drawing, with respective sizes and end connection types. The design criteria should match with the utility ratings, as specified in the contractual agreements, or site conditions. These should also co relate with the process requirements. ACCEPTED" Criteria with a yellow highlighter pen on the Utility List and GA drawing. "NOT ACCEPTED" Criteria corrections with a red highlighter pen on the Utility List and GA drawing. Attach thus marked Utility List and GA drawing labelled as 'DQ Check' to this DQ as an appendix. If any of the utility requirements is not mentioned in the Utility List and GA drawing, then the same should be mentioned in the deviation register. Then the Utility List and/or GA drawing will be revised for the corrections.
Acceptance Criteria	Utility List / GA drawing must mention all the required utilities.

Power Supply Consumption:	3 PH/50 HZ	**Total Load Consumption:**	7.5 KW(10 HP)
Voltage Required:	415 V	**Cable Size Requirement:**	2.5 mm^2 CU.4 CORE

Comments:

	Name	Signature	Date
Executed by			
Reviewed by			

SAFETY VERIFICATION	
Objective	To ensure that the equipment is safe for the Operators and the working environment.
Method	Complete the table below.
Acceptance Criteria	All the requirements are incorporated into the design.

Safety Requirement	Acceptance Criteria	Design Criteria	Pass/Fail
1) Moving Parts	All Moving Parts are Covered and guarded.	The Vacuum pump is completely enclosed in a metal casing/ Compartment.	
2) Noise Levels	Should not exceed 75 decibels averaged over source operative period. At distance of 1 mtr. from the noise source at a height of 1.5 mtr.	PTS should be designed so as not to exceed the pre-defined acceptance criteria for noise levels of below 75 db.	
3) Safety Interlocks	All Safety Interlocks defined in pt. No. 3.7 above are incorporated.	The Safety Interlocks are correctly incorporate per the process flow and inter-linkages.	
4) Safety Standard Required Project Plan	Atex/Ex/ISO 7010:2010/ ISO 9355-1:1999/ ISO 12100-2:2011	Safety Standards are mentioned in GA also as per safety rules design has been changed/Revised	

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10.0 DQ DEVIATION/DEFICIENCIES REPORTS:

Description of deficiency/deviation and date of observation:

Person responsible for corrective action and date assigned for correction:

Comments:

	Name	Signature	Date
Executed by			
Reviewed by			

11.0 ATTACHMENTS REGISTER:

S.No.	Document Name and Description	Document Number	Revision Number
1.	Purchase Order		00
2.	FDS		00
3.	GA Drawing		00
4.	Component list		00
5.	Instrument list		00
6.	Utility list		00

Comments:

	Name	Signature	Date
Executed by (Vendor)			
Approved by (Client)			
Reviewed by **(M/s. ……)**			
Approved by **(M/s. …….)**			