



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT  
FOR  
POWDER TRANSFER SYSTEM**

**PROTOCOL No.:**

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
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**PROTOCOL No.:**

**APPROVALS – .....**

Action	Designation	Name	Date	Signature
Prepared by	QC Engineer			
Approved by	QC Manager			

**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



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**1.0 OBJECTIVES**

Definition of Installation Qualification is:

“The process of confirming that an item of the equipment or of the system, as currently installed, meets its design intensions, specifications and installation requirements.”

The objectives of this Installation Qualification are therefore enumerated as follows:

- To ensure that the equipment/system confirms to the manufacturer’s description and installation requirements.
- To ensure that the equipment/system complies with relevant requirement of current Good Manufacturing Practices for Pharmaceuticals.
- To provide a record of key features of the equipment and components as currently installed.
- To ensure that there is sufficient documentation to enable the equipment to be operated and maintained safely, effectively and consistently.
- To ensure that the equipment is in a satisfactory state to allow the Operational Qualification (OQ) to be performed safely and with consistently repeatable results.

	Name	Signature	Date
Executed By:			
Reviewed By:			
Approved By:			



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**2.0 SCOPE OF VALIDATION:**

The scope of this validation study is the installation of POWDER TRANSFER SYSTEM. Services are considered from within their point of connection to the machine. Inspection and verification of component list, Instrument list, Utility list, As per GA Drawing along with their test certificate verification; those are included in material chart.

**Comments:**

	Name	Signature	Date
Executed By:			
Reviewed By:			
Approved By:			



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**3.0 ABBREVIATIONS AND DEFINITIONS**

- IQ Installation Qualification
- OQ Operational Qualification
- FDS Functional Design Specification

**4.0 RESPONSIBILITIES**

Specific requirements regarding testing of this equipment are:

..... Responsibilities:

- Preparation of the IQ protocol.
- Approval for release of this protocol to M/s. ....for acceptance.
- Installation and Commissioning with respect to the POWDER TRANSFER SYSTEM.
- Performing of all IQ checks and tests with respect to the POWDER TRANSFER SYSTEM.

M/s. .... Responsibilities:

- Performing and reporting all IQ checks with respect to the POWDER TRANSFER SYSTEM to M/s. ....
- Approval of the protocol prior to commencement of the work.
- Final completed approval report of M/s. ....

**Comments:**

Empty box for comments.

	Name	Signature	Date
Executed By:			
Reviewed By:			
Approved By:			



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## 5.0 DATA COLLECTION

1. The Installation Qualification will comprise the approved copy of this protocol and of appended documents. All documentation will be completed, annotated as indicated in this protocol and listed in the appropriate action.
2. All people who enter data in this report will be identified in the appropriate section.
3. All approval signatures are to be made.
4. All data is to be entered in clear handwriting and, where possible, in blue unless otherwise instructed.
5. Any correction to handwritten data will be made by deleting with a single line and initiating and dating the correction. Also a brief reason for the Correction will be given / stated.
6. The protocol completer should enter his initials in the appropriate boxes to indicate the findings. 'Ticks' and 'Crosses' must not be used.
7. The protocol completer should, if necessary, enter comments arising from the findings in the appropriate comment section for the Report Approver's attention. These comments should be continued in an appendix if necessary. Individual comments should be initiated and dated. The reviewers and approvers of the completed report may add initiated and dated responses to the comments if necessary.
8. When each page and/or section is completed, it should be signed and dated by the personnel who carried out the checks.
9. All tests must be carried in sequence shown in this document.
10. The following colour conventions will be used when annotating or verifying drawing, sketches and data.

Verified as correct	: Yellow highlighter
Not verified	: Green highlighter
(Reason for no verification in green ink adjacent to highlighted area)	
Verified as incorrect	: Blue highlighter



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11. Equipment/documents required for completion of IQ

- Tool kit
- Multi meter
- Spirit level
- Tachometer
- Clamp Meter

12. Reference documents required for completion of OQ.

- Installation & Operation maintenance Instructions manual.
- Functional Design Specification.
- As Built GA Drawing.
- Electrical Drawing
- Material Chart with Test Certificates

**Comments:**

--

	Name	Signature	Date
Executed By:			
Reviewed By:			
Approved By:			





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**6.0 CRITERIA FOR ACCEPTABILITY**

The Installation Qualification of the POWDER TRANSFER SYSTEM is considered acceptable if it is found to comply with the mechanical, electrical and safety requirements that it is designed to comply with. It must also meet the requirements specified in this protocol.

**7.0 INTERPRETATION OF RESULTS**

If the results of Installation Qualification activities do not meet the acceptance criteria, a M/s. .... Validation review team will meet to agree on the corrective action.

If the results of all qualification activities are acceptable, then the Installation Qualification is complete.

	Name	Signature	Date
Executed By:			
Reviewed By:			
Approved By:			



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**8.0 DOCUMENTS THAT SHOULD BE AVAILABLE AT THE TIME OF IQ**

Given below are the documents available at the time of the Installation Qualification:

S. No.	Document	Document reference (No., Revision)	Verified Yes/No
1.	Functional Design Specification		
2.	Design Qualification		
3.	Component List		
4.	Instrument List		
5.	Utility List		
6.	Installation Maintenance & Operating Instruction Manual		
7.	As Built Electrical Drawing		
8.	Cable & Pneumatic Tube Schedule		
9.	Material Chart & Test Certificate		
10.	As-built G.A. Drawing		
11.	Warranty Certificate		
12.	Factory Acceptance Test		
13.	Operational Qualification		

**Comments:**

	Name	Signature	Date
Executed By:			
Reviewed By:			
Approved By:			



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**9.0 SERVICES CONNECTION CHECK**

**1. Objective**

Complete the connections of the actual services required and give observations on any discrepancies between them and those recommended by the supplier.

**2. Method**

Access connection terminals/parts by removing guards/panels, if any. Connect respective sources/utilities from battery limit using specified interfaces. Secure tightly and check for leakages. Re-fit safety guards / covers once done.

**3. Acceptance Criteria**

Complete the following table:

Service/Utility	Procedure	Recommended Rating	Verified Value	Verified Yes/No
Electricity	Multimeter / Clamp meter on supply cable	0-40Ampere 415+-10%		
Compressed air	Pressure gauge	6kg/cm <sup>2</sup>		

**Comments:**

	Name	Signature	Date
Executed By:			
Reviewed By:			
Approved By:			



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**10.0 EQUIPMENT COMPONENTS AND INSTRUMENTATION CHECK**

Compare the equipment with the relevant General Assembly and schematic drawings and mark the verified components and instruments as described in these drawings. Ensure that any valves and instruments have identifications numbers which correspond to those shown on the drawings.

Write the words **INSTALLATION QUALIFICATION DRAWING CHECK** on the drawing. Sign and date these marked-up prints when the checks are completed. Also write the protocol title, reference number and the appendix number on the prints.

Attach the marked up prints to this protocol as an appendix.

<b>Drawing. Title</b>	<b>Drawing Number</b>	<b>Revision</b>	<b>Drawing Date</b>	<b>Verified Yes/No</b>
As Built G A Drawing				
Electrical Drawing				

**Comments:**

	<b>Name</b>	<b>Signature</b>	<b>Date</b>
Executed By:			
Reviewed By:			
Approved By:			



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### 11.0 PRE-START UP SAFETY REVIEW PROCEDURE:

Before the equipment is operated, the following safety checks must be completed:

#### 11.1 Site & Leveling

- **Objective:** To ensure that machine is currently sited & levelled.
- **Procedure:** Move the machine to required location as per layout. Level the machine by checking with a spirit level in different locations and directions.
- **Acceptance Criteria:** Machine is at correct location. Machine is levelled in all planes.

#### 11.2 Cleaning

- **Objective:** To ensure that Machine is cleaned properly as required.
- **Procedure:** In accordance with manual dismountable process area parts. Rinse and Clean exposed surfaces of all parts thoroughly. Degrease painted parts using soft cloth.
- **Acceptance Criteria:** Contact parts are cleaned thoroughly. Non-contact area is free of dust & dirt.

#### 11.3 Mechanical

- **Objective:** Visually inspect the installation for damage that may compromise safety during operational qualification work and future operations.
- **Procedure:** Visual inspection & document in format the below.
- **Acceptance Criteria:** All columns in the table should be completed and the tested parts should be identified.

S. No.	COMPONENT	MAKE	MODEL/MOC/SIZE	VERIFIED YES/NO
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S. No.	COMPONENT	MAKE	MODEL/MOC/SIZE	VERIFIED YES/NO
1.	Shell	.....	SS304, 2 Thk	
2.	Bottom Cone	.....	SS304, 2 Thk	
3.	Top Flange	.....	SS304, 12Thk	
4.	Top Dish	.....	SS304, 2 Thk	
5.	Eye Bolt	.....	SS 304, M12	
6.	Lug Pipe	.....	SS 304, 50ODX 2mm Thk	
7.	Sq.Gasket	Acrosil	Food Grade Silicone 8 Width X 8Thk	
8.	Manually Operated Butterfly Valve at discharge	Valfit Engg	4" ID SS 316 With Handle One Side Neck	
9.	Pad Plate for Leg	.....	SS304, 160X75	
10.	Pipe for Leg	.....	SS304, 50X50	
11.	Cartridge Filter	STD	5 Micron (washable)	
12.	Pulsing receiver	.....	SS304 X1.6 Thk	
13.	Solenoid valve	Avcon	SS 304, 1" BSP	
14.	Air Pulsing Manifold	.....	SS304	
15.	Actuator	Rotex	ECF63	
16.	Pneumatic Actuated Ball Valve	Seeco	SS 304, 3" TC End	
17.	Serrated Nozzle with TC	.....	2 ½" x14Swg, SS316	
18.	Actuator	Rotex	ECF50	
19.	Pneumatic Actuated Butterfly Valve at Powder Inlet	Valfit Engg	2 1/2" ID, SS 316	
20.	Pipe with TC	.....	SS316, 2 ½" x14Swg	
21.	Handle	.....	SS304	
22.	Motor for Vacuum Pump	HMM	HP-10,RPM-1450, V-415,HZ-50, FR.SIZE-132M	
23.	Vacuum Pump	Comp-Vac Technology Pvt. Ltd.	SGR-116,CFM-400	
24.	Operating Panel	Flame & Explosion Proof Equip. Mfg. Co.	FLP+EX-150	



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#### 11.4 Utilities & Services

- **Objective:** Visually inspect the utilities and services installation for any damage that may compromise safety during operation of the unit.
- **Method:** Visual verification & co-relation with GA Drawing.
- **Acceptance Criteria:** Utility and Services Installations are compatible with information in GA Drawing, Manual and prevalent site standards.

#### 11.5 Electrical and Mechanical safety study

Document reference (No, Revision)	Reference Section	Verified Yes/No
Functional Design Specification (FDS)		
Installation Maintenance & Operating Instruction Manual		

**Comments:**

	Name	Signature	Date
Executed By:			
Reviewed By:			
Approved By:			



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12.0 PRODUCT CONTACT AND NON-CONTACT PARTS MOC  
VERIFICATION

PART	MATERIAL		CONDITION	VERIFIED
	Description	Specified		
<b>Contact Parts</b>				
Shell	SS 304			
Cone	SS 304			
Dish	SS 304			
Top Flange	SS 304			
Butterfly Valve	SS 316			
Gasket	Food Grade Silicone			
<b>Non-Contact Parts</b>				
Leg	SS 304			
Pulsing receiver	SS 304			

Comments:-

	Name	Signature	Date
Executed By:			
Reviewed By:			
Approved By:			





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**13.0 INSTALLATION OPERATION AND MAINTENANCE MANUAL VERIFICATION**

The manual should give detailed and complete information and instructions on the Installation, Operation and Maintenance of the equipment.

<b>Section</b>	<b>Verification</b>	<b>Date</b>
Unpacking and rechecking instructions		
Working principle		
Installation instructions		
Operation instructions		
Maintenance		
Preventive Maintenance Schedule		

**Comments:**

	<b>Name</b>	<b>Signature</b>	<b>Date</b>
Executed By:			
Reviewed By:			
Approved By:			



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**14.0 LIST OF APPENDICES**

Appendix No.	Document	Ref. section	Confirmation to proceed for OQ Yes/No
1.	Purchase Order (PO)	1	
2.	Quality Assurance Plan (QAP)		
3.	Functional Design Specification (FDS)		
4.	Approved GA Drawing		
5.	Design Qualification (DQ)		
6.	Component List (CL)		
7.	Instrument List (IL)		
8.	Utility List (UL)		
9.	Installation Maintenance & Operating Instruction (IMOI)		
10.	Electrical Wiring Diagram	2	
11.	Cable & Pneumatic Schedule		
12.	Material Chart With MOC & Bought out Item Test Certificates & Manual	3	
13.	As Built GA Drawing		
14.	Warranty Certificate(WC)		
15.	Factory Acceptance Test (FAT)	4	
16.	Operation Qualification (OQ)		

**Comments:**

	Name	Signature	Date
Executed By:			
Reviewed By:			
Approved By:			



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**15.0 DEVIATION FROM DESIGN/DEFICIENCIES**

Description of deficiency/deviation and date observed:

Person responsible for corrective action and date assigned:

	Name	Signature	Date
Executed By:			
Reviewed By:			
Approved By:			



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**16.0 REPORT ON CORRECTIVE ACTIONS TAKEN WITH DATE**

**Comments:**

--

	Name	Signature	Date
Executed By:			
Reviewed By:			
Approved By:			



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**17.0 CONCLUSION**

**Installation Qualification Approval:**

The data required for the Installation Qualification of the equipment has been collected and entered in the relevant sections of this protocol. Satisfactory results have been obtained except for the items identified for further actions. These are listed as follows:

**Comments:**

--

	Name	Signature	Date
Executed By:			
Reviewed By:			
Approved By:			



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**18.0PRE APPROVAL**

Installation and commissioning of the POWDER TRANSFER SYSTEM, including satisfactory resolution of all discrepancies noted during execution, will be documented below, signed by the personnel with overall review responsibility for the protocol and by the M/s. ....  
Authorised signatories who approved the protocol, Hence this document before being effective shall be approved by the QA/QC team of M/s. ....and authorised by the appropriate project consultant authority signatories of IQ protocol to confirm acceptability to proceed to Operational Qualification (OQ).

Acceptance Criteria	Agreement YES/NO
1. POWDER TRANSFER SYSTEM is approved for OQ following correction of all deviations noted during IQ to be complied.	
2. POWDER TRANSFER SYSTEM is not approved & will require repeat IQ following correction of all deviations.	
3. Approval for IQ protocol to confirm acceptability to proceed to Operational Qualification (OQ)	

**APPROVALS –.....:**

Action	Designation	Name	Date	Signature
Executed By	Service Engineer			
Approved by	Sr. Service Engineer Site In charge			

**APPROVALS – CLIENT: M/s. ....**

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



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**19.0 POST APPROVAL AND FINAL REPORT**

M/s. .... warrants that the POWDER TRANSFER SYSTEM is installed properly in a satisfactory state to allow the Operational Qualification (OQ) to be performed safely and with consistently repeatable results. M/s. .... Personnel and appropriate project consultant authority signatories of IQ protocol to confirm acceptability to proceed to Operational Qualification (OQ).

**Summary:**

**Analysis & Evaluation of Data**

**Comments:**

<b>Action</b>	<b>Functional Head of the Department</b>	<b>Name</b>	<b>Signature</b>	<b>Date</b>
Authorized by	Engineering			
Authorized by	Production			
Authorized by	Quality Assurance			