



PHARMA DEVILS

**PERFORMANCE QUALIFICATION REPORT
FOR
POWDER TRANSFER SYSTEM**

PROTOCOL No.:

**OPERATIONAL QUALIFICATION
FOR
POWDER TRANSFER SYSTEM**

APPROVALS – VENDOR:.....

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

APPROVALS – CLIENT:

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. OBJECTIVES:

1. This document defines the procedure for and the record of the Operational Qualification activities for the POWDER TRANSFER SYSTEM.
2. This document describes the control performance of the POWDER TRANSFER SYSTEM.
3. This document is intended to be of use to engineering staff of both M/s. & of as quantitative definitions of the expected control performance of the deliverable system.
4. The performance data in this document should satisfy the Requirement Specifications of M/s. Wherever a difference/deviation exists between the requirement specifications and this document, the presence of the signature of a representative of M/s. On the front cover indicates an agreement that the performance quoted in this document is acceptable.

2. SCOPE:

1. This document refers only to the POWDER TRANSFER SYSTEM. Qualification of associated instrumentation and ancillary equipments is covered in separate documents.
2. This document applies specifically to POWDER TRANSFER SYSTEM.

3. ASSUMPTIONS, LIMITATIONS AND EXCLUSIONS:

It is assumed that all manufacturing operations, adjustments, inspection and installation qualification have been performed prior to undertaking the Operational Qualification of the POWDER TRANSFER SYSTEM.



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4. RESPONSIBILITIES:

Specific requirements regarding the testing of this equipment are:

Responsibilities – M/s.:

- Preparation of the OQ protocol.
- Approval for release of this protocol to M/s. for acceptance.
- Performing and reporting all OQ checks in respect of the POWDER TRANSFER SYSTEM.

Responsibilities-M/s.

- Approval of the OQ protocol prior to commencement of the work.
- Performing and reporting all OQ checks in respect of the POWDER TRANSFER SYSTEM.
- Final completed report and approval.

Comments:

	Name	Signature	Date
Executed By			
Reviewed By			
Approved By			



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5. DATA COLLECTION

1. This Operational Qualification will comprise of the approved copy of this protocol and of appended documents. All documentation will be completed and annotated as indicated in this protocol and listed in the corresponding check/action.
2. All people who enter data in this report will be identified in the assigned section.
3. All approval signatures are to be made.
4. All data is to be entered in clear handwriting and in blue unless otherwise instructed.
5. Any correction to handwritten data will be made by deleting with a single line and signing and dating the correction. Also, a brief reason for the Correction will be stated.
6. The person (Bectochem side) completing the protocol should enter his findings in the verification boxes to indicate the findings. 'Ticks' and 'Crosses' must not be used.
7. The protocol completer should, if necessary, should 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 signed and dated. The reviewers and approvers of the completed report may add signed 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 drawings, sketches and data.
 - Verified as correct : Yellow highlighter
 - Not verified : Green highlighter.
 - Reason for no verification : Green ink adjacent to highlighted area.
 - Verified as incorrect : Blue, highlighter
11. Equipment/documents required for completion of OQ
 - Tool kit
 - Multi-meter
 - Spirit level
12. Reference documents required for completion of OQ.
 - Functional Design Specification.
 - Installation & Operation maintenance Instructions manual.



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- Installation Qualification document.

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6. CRITERIA FOR ACCEPTABILITY:

The Operational 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. INTERPRETATION OF RESULTS:

- If the results of the Operational Qualification activities do not meet the acceptance criteria, M/s. Validation Review team will meet to agree corrective action.
- If the Results of all qualification activities are acceptable, then the Operational Qualification is complete.

8. ADDITIONAL DOCUMENTATION REQUIRED:

- POWDER TRANSFER SYSTEM Operating manual.

9. PRE-QUALIFICATION REQUIREMENTS:

- Installation Qualification **MUST** be completed before commencing the Operational Qualification.
- Ensure that all the tools are removed from the equipment before beginning the OQ.
- Ensure that the Emergency STOP button is released.
- All external equipment is to be disconnected. Ensure that any external STOP circuit is overridden.
- Mains power supply to the machine must be switched OFF.
- All drives are free from external hindrance.

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**10. 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.	Installation Qualification		

Comments:

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Reviewed By:			



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11. TESTS:

Test 11.1: Main Power Supply:

Objective: To ensure correct operation of the machine.

Method: Connect the main power supply to the control cum operating panel of the machine.

Acceptance Criteria: Check that there is no power supply to the machine when M.C.B. is off and vice versa. Check that the main motor of the POWDER TRANSFER SYSTEM rotate in the clockwise direction by provide the required input supply of suitable frequency of motor as per the utility mentioned in the utility list/cable schedule.

Test 11.2: Operating Panel Function Test:

Objective: Operation of control cum operating Panel

Method: Follow the Standard Operating Procedure:

Acceptance Criteria: Smooth function of control cum operating panel carried out and achieved as per required parameter.

Wiring Tug Test and Operating Panel Function Test

Objective	Confirm that all the wires are connected to the electrical switchgears tightly. Continuity of electrical switchgears is verified for proper connections with respect to the equipment.
Method	Lightly pull all the wires connected to the electrical switchgears one by one testing for any loose connections. Redo the connection, if any is found loose. Any discrepancies and deviations are to be noted in this document in the deviation report. Check the operation of unit as per the start sequence detailed in the manual. Any discrepancies and deviations are to be noted in this document in the deviation report.
Acceptance Criteria	Smooth function of control cum operating panel carried out and achieved as per required parameter.

Comments:

	Name	Signature	Date
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Reviewed By			
Approved By			

Test 11.3: Equipment Control Functions and Interlocks Verification Test:

Objective: Verification of equipment controls and interlocks function

Method: Follow the Machine FDS and process description

Acceptance Criteria: Smooth operation carried out and milling is achieved as per required parameter.

Equipment Control Functions and Interlocks Verification	
Objective	To verify that the equipment controls and interlocks function are as specified in the Machine controls & Logics.
Method	Take a copy of the Machine FDS and process description. Run the machine. By operating, verify and check whether all the controls and interlocks are in place by simulating the conditions. Any discrepancies and deviations are to be noted in this document in the deviation report.
Acceptance Criteria	The Controls and interlocks should function as per the Machine FDS and process description.

INTERLOCKS		
INTERLOCKS	Acceptance Criteria	Complies Yes/No
Emergency Stop	Once pressed the system stops.	
Timer	VACUUM SOV should be ON as per the settable time. At the time of VACUUM SOV should be close and Pulsing SOV should be open.	

Comments:

	Name	Signature	Date
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Reviewed By			
Approved By			

Test 11.4 Equipment Operation Verification without Load:

Objective	To verify the operation of the machine is as per Manual/FDS & Process requirements.
Method	Check the operation of unit as per the start sequence detailed in the manual. Fill out the table as per attachment. Any discrepancies and deviations are to be noted in this document in the deviation report.
Acceptance Criteria	The equipment parameter without load should confirm to the rated capacities of the process equipment needs to be

Motor Performance checks Without Load

Operations	Speed (rpm)	Time interval (Hrs)	Temp °C	Vibration	Noise Level (db)	Motor Current (Amps)
Motor performance						R: Y: B:

Comments:



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Test 11.5 Equipment Operation Verification with Load:

Objective	To verify Performance of PTS.	
Method	Use dummy powder for PTS operation check. Check the transfer of powder in the PTS. Monitoring current drawn by motor, Sound, Vibration, overheating of the components which are Documented in the table below.	
Acceptance Criteria	Current should not exceed the rated Amp. Of motor Sound must not exceed 80db at 1 mtrs linear distance and 1.5 mtrs. Vertical distance from source of sound. Temperature should exceed Lubricant rated temperature or AMBIENT $\pm 30^{\circ}\text{C}$	
DESCRIPTIONS	ACCEPTANCE	Noted Amps.
1. Run the PTS	Rated Current	
	Pump motor current	R: Y: B:
DESCRIPTIONS	ACCEPTANCE	VERIFIED (YES/NO)
Temperature		
Motor		
Pump		
Vibration		
Complete unit		

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	Name	Signature	Date
Executed By			
Reviewed By			
Approved By			



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12. PRE APPROVAL

Operational Qualification of the POWDER TRANSFER SYSTEM includes satisfactory resolution of all discrepancies noted during execution, will be documented below, and 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.

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 not require repeat IQ following correction of all Deviations.	
3. Approval for OQ protocol to confirm acceptability of POWDER TRANSFER SYSTEM	

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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13. POST APPROVAL

The performance data in this document with respect to POWDER TRANSFER SYSTEM should satisfy the requirement specifications of M/s. Wherever a difference/deviation exists between the requirement specifications and this document, the presence of the signature of a representative of M/s. On the front cover indicates an agreement that the performance quoted in this document is acceptable. M/s. Personnel signatories and also appropriate project consultant authority signatories of OQ protocol to confirm acceptability of POWDER TRANSFER SYSTEM.

Acceptance Criteria	Agreement Yes/No
1. POWDER TRANSFER SYSTEM is approved for OQ following correction of all deviations noted during OQ to be complied.	
2. POWDER TRANSFER SYSTEM is not approved & will require repeat OQ following Correction of all deviations.	
3. Approval for OQ protocol to confirm acceptability of POWDER TRANSFER SYSTEM	

Action	Functional Head of the Department	Name	Signature	Date
Authorized by	Engineering			
Authorized by	Production			
Authorized by	Quality Assurance			