PERFORMANCE QUALIFICATION

PROTOCOL

FOR

DEDUSTING TUNNEL

DATE OF QUALIFICATION	
SUPERSEDES	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR DEDUSTING TUNNEL	PROTOCOL No.:

PROTOCOL CONTENTS

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1.0 PROTOCOL PRE –APPROVAL :

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (WAREHOUSE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing as per the parameter defined in operational qualification and that it gives result as per the predetermined acceptance criteria.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.
- The document also provides the observed and obtained values indicating compliance to the PQ Protocol.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the De-dusting conveyor tunnel.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.

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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Performance Qualification Protocol cum Report. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity • Monitoring of Performance Qualification.
Production	• Review of Protocol cum Report. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of Protocol cum Report • Analytical Support (Microbiological Testing / Analysis)

5.0 EQUIPMENT DETAILS:

Equipment Name	DE-DUSTING TUNNEL
Equipment Id No.	
Manufacturer's Name	
Supplier's Name	
Model	GMP Model
Location Of Installation	Warehouse

6.0 SYSTEM DESCRIPTION:

De-dusting Tunnel is recommended where materials (on pallets) have to be moved from warehouse to class D areas according to GMP (Class ISO 8 according to ISO 14644-1). De-dusting tunnel is made of AISI 304 stainless steel casing. It is constructed by cutting, hemming, bending, spot welding and bolt junctioning where necessary. The welded pieces are strengthened by subsequent silicone sealing. The electric control panel is placed outside the box and it is easy to reachable.

The filtered air is delivered by the adjustable nozzles positioned on both sides and on the ceiling of the unit. The high velocity air jets remove most of the contamination dust from the pallet, that is positioned inside the box.

The air is drawn through the EU-7 & EU-4 pre-filters. The air flow rate and the nozzles position have been designed in order to assure that the pallet is completely invested by air jets. Light fixtures are installed on the ceiling panel of the shower for internal lighting.

7.0 REASON FOR QUALIFICATION:

After completion of the Operation Qualification of the equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

Warehouse Quarantine.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every two years.
- After any major breakdown or after major modification.
- After Change of Location

10.0 PRE-QUALIFICATION REQUIREMENTS:

10.1 Verification of Documents:

Verify that the DQ/IQ/OQ of the HVAC System has been executed and approved.

Verify that SOP for Operating, Cleaning and Preventive Maintenance of the HVAC System has been prepared.

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	OQ Protocol Cum Report				
4.	PQ Protocol				
5.	Draft SOP for operating & Cleaning of De-dusting Tunnel.				
6.	Draft SOP for Preventive Maintenance of De-dusting Tunnel				

11.0 TESTS AND CHECKS:

Objective: To determine that the system/equipment perform as intended by repeatedly running the system on it intended schedules and recording all relevant information and data. Result must demonstrate that performance consistently meet pre-determined specifications under normal conditions and where appropriate for worst case situation.

Scope: To be performed after the installation and operational qualification have been completed and approved. To be performed after installation, modification or relocation and for revalidation at appropriate intervals.

Procedure: To demonstrate the performance of smooth running of De-dusting conveyor tunnel, conveying bulk container through tunnel. The movement of container whether easily moving or not. Keeping observation on how much dust expels form surface area of raw material container.

A. Evaluation-I

S.No.	Weight of Container (Kgs)	Free movement of Container YES/NO
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

B. Evaluation- II

S.No.	Weight of Container (Kgs)	De dusted on Container YES/NO
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

Checked By
(Production)
(Sign/Date) ……

Verified By
(Quality Assurance)
(Sign/Date)……

Inference:……

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Reviewed By:
(Manager QA)
(Sign & Date)_____

12.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan.
- Schedule-M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.
- The following references are used for addition guidance
- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition/March 2001.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.

13.0 DOCUMENTS TO BE ATTACHED:

- Operation And Maintenance Manual
- Final SOP's.
- Any Other Relevant Documents

14.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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15.0 CHANGE CONTROL, IF ANY:

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

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17.0 CONCLUSION:

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18.0 RECOMMENDATION:

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19.0 ABBREVIATIONS:

No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
IQ	:	Installation Qualification
OQ	:	Operational Qualification
EQ	:	Equipment
BSC	:	De-dusting Tunnel
MOC	:	Material of construction
NLT	:	Not less than
HP	:	Horse power
KW	:	Kilo watt
SS	:	Stainless steel
ID.	:	Identification
Kg	:	Kilo gram
Ltrs	:	Liters
mm	:	Millimeter
MCB	:	Miniature circuit break