PERFORMANCE QUALIFICATION PROTOCOL FOR PRE-MIX FILLING MACHINE

EQUIPMENT ID No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR PRE-MIX FILLING MACHINE	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR PRE-MIX FILLING MACHINE	PROTOCOL No.:

1.0 PROTOCOL APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
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 Performance 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.

3.0 SCOPE:

This Protocol is applicable for performance qualification of Pre-Mix Filling Machine installed in Pre Mix filling area.

4.0 RESPONSIBILITY:

The Qualification team, 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. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Reviewing of qualification Protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.
Quality Control	• Review of Performance Qualification report. • Approval of report post approval.

5.0 EQUIPMENT DETAILS:

Equipment Name	Premix Filling Machine
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Location of Installation	

6.0 SYSTEM DESCRIPTION:

The Pre-Mix Filling packing machines are nozzle filling machines. They are specially designed for filling particular quantity of the solution, suspension and other liquid phase in the bottle. The machine is ideal for the free flow liquid.

7.0 REASON FOR QUALIFICATION:

After completion of the Operational 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:

Dry Powder Injection Area

9.0 FREQUENCY OF QUALIFICATION:

- Once in two year time period.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE-QUALIFICATION REQUIREMENTS:

10.1 SYSTEM PRE-REQUISITES:

Verify that the DQ / IQ / OQ of the Pre- Mix filling machine have been executed and approved.

Verify that the SOP for Operating, Cleaning and Preventive Maintenance of the Pre-Mix filling machine has been prepared.

S.No.	DESCRIPTION OF PRE-REQUISITE	COMPLETED (YES / NO)	CHECKED BY ENGINEERING SIGN / DATE	VERIFIED BY QA SIGN / DATE
	Verify that the DQ / IQ / OQ of the Pre-Mix filling machine has been executed and approved.			
1.	DQ Protocol Document No.:			
2.	IQ Protocol Document No.:			
3.	OQ Protocol Document No.:			
4.	SOP of “Operation and Cleaning of Pre-Mix filling machine”			

11.0 TESTS & CHECKS:

11.1 PURPOSE:

The Pre-Mix filling machine is mainly used for filling of Liquid. The objective of the test is to determine whether the machine is able to properly fill the liquid in bottle.

11.2 PROCEDURE:

To determine that the system / equipment perform as intended by repeatedly running the system on its intended schedules and recording all relevant information and data. Result must demonstrate that performance consistently meets pre-determined specification under normal condition, and where appropriate for worst case situations. Three batches of same product or different product shall be considered for performance qualification. To evaluate the performance of equipment machine shall be operated at different speeds in three different batches and data shall be recorded..During this, following parameters shall be checked:

- Average fills and fill variation of fill bottle.

11.3 ACCEPTANCE CRITERIA:

Filled bottle should comply with the limits of Fill variation.

11.4 PROCEDURE:

Run for at least 3 batch, recording all required data and any deviations to the procedure

12.0 CHECKLIST OF ALL TESTS & CHECKS:

The following table lists the number of tests / samples to be carried out & comments on the sample record sheet.

TESTS OR CHECKS	EXECUTED [Y/N]	COMMENT
Average fill weight and weight variation of fill bottle		

13.0 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 to give addition guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5: Commissioning and Qualification Guide, First Edition / March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, Beta. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, April 1, 1998.
- 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.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.

14.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

15.0 NON COMPLIANCE:

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16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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17.0 CHANGE CONTROL, IF ANY:

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18.0 REVIEW (INCLUSIVE FOLLOW UP ,ACTION):

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19.0 CONCLUSION:

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20.0 RECOMMENDATION:

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21.0 ABBREVIATIONS:

Sr.	:	Senior
No.	:	Number
gm	:	gram
BSS	:	British Standard Sieve
BMR	:	Batch Manufacturing Record
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
GMP	:	Good Manufacturing Practices
SOP	:	Standard Operating Procedure
RH	:	Relative Humidity
^{o}C	:	Degree Centigrade
mm	:	Millimeter
Amp.	:	Amper
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification