PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC TWO HEAD CAPPING MACHINE

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC TWO HEAD CAPPING MACHINE	PROTOCOL No.:

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PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC TWO HEAD CAPPING 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 Automatic Two Head Capping Machine installed in Lotion filling area. The equipment is to be used for Sealing of bottle.

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	Automatic Two Head Capping Machine
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Location of Installation	

6.0 SYSTEM DESCRIPTION:

The Automatic Two head capping Machine is compact unit totally made of SS structure with height adjustment legs are provided to adjust the machine height and highly efficient machine with elegant look. This multifunctional multi featured machine meets the GMP requirements of labeling for glass and plastic Bottles. The machine requires manual loading and automatic unloading of Bottles.

Two Head capping machine operates in a continuous motion, whereby bottles are fed into the capping area by means of a timing screw, which accelerates and separates the bottles to a pitch which matches the infeed star wheel. Bottles are then transferred through the system from the infeed star wheel via the turret star wheel, onwards to the outfeed star wheel, where they exit the machine. During this process, the caps are simultaneously sorted and fed into the machine along a linear belt into the cap star wheel, where the capping heads descend and picks up the waiting cap and applies it to one of the pre-positioned bottles to a predetermined torque. The whole machine is made of 304 stainless steel and aluminum materials, the standardized design, interchangeable parts, completely according with GMP requirements.

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:

Packing Hall.

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 TRAINING: Training shall be given to the concerned persons and details recorded into the Qualification Report.

10.2 SYSTEM PRE-REQUISITES:

Verify that the DQ / IQ / OQ of the Automatic Two Head Capping Machine have been executed and approved.

Verify that the SOP for Operating, Cleaning and Preventive Maintenance of the Automatic Two Head Capping 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 Automatic Two Head Capping 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 Automatic Two Head Capping Machine”			

11.0 TESTS & CHECKS:

11.1 CONVEYER SPEED TEST:

Objective:

The objective of the test to determine the effect of Conveyer speed on product quality.

Scope:

The Scope of this test limited to the Dry Powder Filling Area.

Procedure:

- Switch on the conveyer Belt Machine.
- Operate the machine as per respective SOP.
- Set the Minimum, Standard and Maximum speed of Conveyer Belt.
- Put the Bottles on the conveyer belt.
- Check the effect of speed on bottle.
- The result record into the A**nnexure-I.**

Acceptance criteria: The conveyer belt should not affect the product quality.

11.2 LEAK TEST:

Objective:

The objective of the test to determine the leakage in bottle.

Scope:

The Scope of this test limited to the Dry Powder Filling Area.

Test Instrument:

Leak Test Apparatus

PROCEDURE:

- The test shall be performing at the preset speed.
- The test shall be perform on 3 consecutive batches.
- Switch "ON" the machine & operate as per SOP.
- Set the Temperature at 90°C -100°C.
- Collect the 10 bottles continuous initial, middle and Final and each variability.
- Perform leak test at specified in BPR.
- Record the data in A**nnexure-III**.

11.3 ACCEPTANCE CRITERIA:

Leakage should not observed.

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
CONVEYER SPEED TEST		
LEAK TEST		

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:

All the Non compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA shall study the impact of deviation. If deviation is acceptable and it does not have an impact on operation as well as on performance of the machine, prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA shall study the impact of change. If change is acceptable and it does not have an impact on operation as well as on performance of the machine, prepare final conclusion.

18.0 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
Pvt.	:	Private
Ltd.	:	Limited

19.0 ANNEXURE:

S.No.	Title
1.	Training Record
2.	Result of Conveyer Speed Test
3.	Result of Leak Test

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC TWO HEAD CAPPING MACHINE	PROTOCOL No.:

Annexure-I
(Training Detail)

S.No.	Name	Department	Sign.	Duration	Remarks

Trainer Name:

Date & Sign:

Annexure-II
(Result of Conveyer Speed Test)

Product Name: **Batch No.:**

Manufacturing date: **Expiry Date:**

At Minimum Speed (30 feet/min):

Date	Interval	Qty. Taken	Leakage	Rejected	Pass	Checked By	Verified By
	Initial						
	Middle						
	Final						

At Standard Speed (40 feet/min):

Date	Interval	Qty. Taken	Leakage	Rejected	Pass	Checked By	Verified By
	Initial						
	Middle						
	Final						

At Maximum Speed (50 feet/min):

Date	Interval	Qty. Taken	Leakage	Rejected	Pass	Checked By	Verified By
	Initial						
	Middle						
	Final						

Checked By
Production
Sign/Date…….

Verified By
Quality Assurance
Sign/Date……

Inference:……..……

……

……

Reviewed By:_____
Manager QA
Sign / Date

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC TWO HEAD CAPPING MACHINE	PROTOCOL No.:

(Result of Leak Test)

Product Name: **Batch No.:**

Manufacturing date: **Expiry Date:**

At Minimum Temperature (90°C):

Date	Interval	Qty. Taken	Leakage	Rejected	Pass	Checked By	Verified By
	Initial						
	Middle						
	Final						

At Standard Temperature (95°C):

Date	Interval	Qty. Taken	Leakage	Rejected	Pass	Checked By	Verified By
	Initial						
	Middle						
	Final						

At Maximum Temperature (100°C):

Date	Interval	Qty. Taken	Leakage	Rejected	Pass	Checked By	Verified By
	Initial						
	Middle						
	Final						

Checked By
Production
Sign / Date……

Verified By
Quality Assurance
Sign / Date…….

Inference:……..……

……

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Reviewed By:_____
Manager QA
Sign / Date