INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC TWO HEAD CAPPING MACHINE

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

PROTOCOL CONTENTS

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC TWO HEAD CAPPING MACHINE	PROTOCOL No.:

1.0 PRE-APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To carry out the Installation Qualification of Automatic Two Head Capping machine used in Production, "The process conforming that an item of equipment, or other system, as currently installed, meets its design qualification".
- To confirm that the equipment and its components are as per the Specifications and Installed as per the Approved Design and complies with GMP practices.
- To prove that each Operation proceeds as per the Design Specification and the tolerances prescribed there in the document, are the same at utmost transparency.
- To ensure that there is sufficient information available to enable the equipment to operate and maintain safely, effectively and consistently.

3.0 SCOPE:

- The Protocol covers all aspects of Installation Qualification of Automatic two Head capping machine used in Production.
- To verify that the correct hardware has been installed, system initializes correctly.
- To record the as built drawing numbers of equipment drawing, P & ID and circuit diagram.

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 and Approval of the Installation Qualification Protocol. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Process.
Production	• Giving clearance to install the unit. • Execution of Installation Qualification activity. • Ensure that the equipment is installed as per protocol. • Review and Approval of Protocol cum report.
Engineering	• To co–ordinate and support Installation Qualification activity. • Calibration of Process instruments. • Ensure that the equipment is installed as per protocol. • Review and Approval of Protocol cum report.

5.0 EQUIPMENT DETAILS:

Equipment Name	Automatic two Head capping machine
Equipment	
Manufacturer's Name	Bhavani Engineers Pvt. Ltd.
Supplier's Name	Bhavani Engineers Pvt. Ltd.
Location of Installation	Filling Line

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 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P& ID).
- Electrical circuits diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction of components.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 GENERAL CHECKS AND LOCATION SUITABILITY:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN / DATE
Leveling	Should be properly balanced and Leveled		
Edges of parts	The Metal parts should be properly grounded without any sharp edges		
Welding of Joints	Welding of joints should be without any Welding Burrs		
Place of Installation			
Room Condition	General working condition.		
Illumination in area	Above 300 Lux inside the cubicle.		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

Checked By
Production
Sign/Date:…….

Verified By
Quality Assurance
Sign/Date: …….

Inference:

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Reviewed By
Manager QA
Sign/Date: _____

8.2 EQUIPMENT VERIFICATION:

Before the equipment is operated, certain checks are to be completed:

Installation Checks	Acceptance Criteria	Observation	Observed by Engineering Sign / date
Conveyor Motor	Make : Rotomotive S/No. 1046076 0.25 HP/0.18KW/0.5A/230-400V/3 Phase/ 50 Hz/1380RPM		
Main Motor	Make : Rotomotive S/No. M02146603 0.25 HP/0.75KW/0.5A/230-400V/3 Phase/ 50 Hz/1380RPM		
Main Motor A.C. Drive	Make: Delta 1 HP, 220-240V Input : Single Phase Output: 3 Phase		
Conveyor Motor A.C. Drive	Make: Delta 0.5 HP, 220-240V Input : Single Phase Output: 3 Phase		
Conveyor Gear Box	Make : Rotomotive Gear Box Ratio : 15:1		
Main Gear Box	Make : Rotomotive Gear Box Ratio :40:1		
Contactor	Make : C & S		
M.C.B.	Make : C & S		
Vibrator Cars	Make : Kamo core		
Speed Pot:	Make : Potel		
ELECTRICAL INSTALLATION:			
Electrical Supply	3 Phase		

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC TWO HEAD CAPPING MACHINE	PROTOCOL No.:

Installation Checks	Acceptance Criteria	Observation	Observed by Engineering Sign / date
	Voltage- 400 V Frequency- 50 Hz		
Electrical connections have been provided and secured.	Should be provided & secured		
All components in the panel are properly secured	Should be secured		
All terminals are tightened	Should be tightened		

Checked By
Production
Sign / Date:_____

Verified By
Quality Assurance
Sign / Date:_____

Inference:……..

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Reviewed By
Manager QA
Sign / Date:_____

8.3 INSTALLATION VERIFICATION:

The components of the system are inspected so as to verify that they are present and documented properly. Any incorrect installations or any deviations from specification are to be documented.

S.No.	VARIABLE	OBSERVATION
1.	Check the proper mechanical installation of Automatic two Head capping machine	
2.	Check the proper alignment of Automatic Two Head Capping machine.	
3.	Check the proper electrical installation of Automatic two Head capping machine	
4.	Check the proper Mechanical Safety of Automatic two Head capping machine	
5.	Check the proper service connection such as compressed air supply, and illumination of Automatic two Head capping machine	
6.	Check the parts are working properly	
7.	Check the equipment is free from any defects	
8.	Check the finishing of product contact parts	
9.	Check that all parts are getting lubricated	

Checked By
Production
Sign/Date: ……

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Sign/Date: ……

Inference:

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8.4 VERIFICATION OF MATERIAL OF CONSTRUCTION:

S.No.	Parts name	MOC	Observation	Checked By Engineering Sign / Date
1.	Machine shell	SS304		
2.	Conveyer	AISI 316		
3.	Star wheel	SS 304		
4.	Capping Bowl	AISI 316		
5.	Platform	SS304		
6.	Turret	AISI 316		
7.	Cabinet	Acrylic		

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign / Date: ……

8.5 SAFETY TESTING:

Item	Acceptance criteria	Observation	Observed by Engineering Sign/date
Well embedded equipment	For proper sifting		
Safety Cabinet	Acrylic safety cabinet should be providing for safety work.		
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine (panel and motors).		
Guards	Guards for all moving parts Should be provided For Motor safety		
Start On / Off switch: To stop the process immediately	Should be provided For equipment and operator safety		
MCB for electrical overload	Should be properly installed		

Checked By
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Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign / Date: ……

9.0 REFERENCES:

- 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.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificates of MOC
- Calibration certificates

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
GMP	:	Good Manufacturing Practice
WHO	:	World Health Organization
P & ID	:	Piping and Instrumentation diagram
RH	:	Relative Humidity
^{o}C	:	Degree Centigrade
DQ	:	Design Qualification
mm	:	Millimetre
HP	:	Horse Power
RPM	:	Revolution per Minute
Amp.	:	Ampere
SS	:	Stainless Steel
Kg	:	Kilogram
Hr.	:	Hour
MOC	:	Material of construction
FDA	:	Food and Drug Administration
EU	:	European Union
IQ	:	Installation Qualification
MCB	:	Miniature Circuit Breaker
V	:	Volts
IQ	:	Installation Qualification

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

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HEAD (QUALITY ASSURANCE)			