INSTALLATION QUALIFICATION PROTOCOL FOR BOTTLE SEALING MACHINE (ROPP)

Equipment ID	
Equipment Location	**Sealing machine Area**
Equipment Make	**JP machine tools**
Document No.	
Reason For Qualification	**New Equipment**

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL FOR BOTTLE SEALING MACHINE (ROPP CAP)	PROTOCOL No.:

TABLE CONTENT

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL FOR BOTTLE SEALING MACHINE (ROPP CAP)	PROTOCOL No.:

1.0 PRE-APPROVAL

Signing of this Installation Qualification Protocol indicates agreement with the Validation Master Plan approach of the equipment. Further if any changes in this protocol are required, protocol will be revised and duly approved.

PREPARED BY:

Organization	Name	Signature	Date
Production			

CHECKED BY:

Organization	Name	Signature	Date
Engineering			
Production			
Quality assurance			

APPROVED BY:

Organization	Name	Signature	Date
Head Engineering			
Head Manufacturing			

AUTHORISED BY:

Functional area	Name	Signature	Date
Head Quality			

2.0 OBJECTIVES

The objectives of this Installation Qualification (IQ) are as follows:

- To verify that the ROPP Bottle sealing machine in ……; Tablets, Capsules & Dry Syrup, Dry injection and Oral Manufacturing Facility has been installed in accordance with the set acceptance criteria and meets GMP requirements.
- To verify that there is sufficient and accurate information to operate and maintain the system reliably and reproducibly.
- To verify that the requirements specified at the time of purchase are met in the delivered and installed item. Purchase Order and Equipment Specifications have been used to prepare this Protocol. Confirmation of the installed system to pre-determined specifications will verify that user requirements have been met.

3.0 SCOPE

This protocol covers all aspects of Installation Qualification for the ROPP bottle sealing machine serving the ……; Tablets, Capsules & Dry Syrup, Dry Powder injection and Oral Manufacturing Facility. Scope incorporates qualification of all ROPP Bottle sealing machine components such as Chute, orienter, Head, tooling components etc.

This protocol will define the methods and documentation used to qualify the ROPP Bottle sealing machine for IQ. Successful completion of this protocol will verify that the ROPP Bottle sealing machine meets all acceptance criteria and is ready for Operational Qualification.

4.0 RESPONSIBILITIES

All work is to be performed under ……. oversight and according to ……. approved procedures.
The following are the primary responsibilities of the …… Validation Personnel

- Preparation, Review and submission of IQ Protocol.
- Ensures that the protocol is in compliance with current policies and procedures.
- Ensures that the content is sufficient, clearly defined technically sound and accurate.
- Ensures compliance with design specifications.
- Overall cGMP compliance for IQ
- Review and Pre-Approval of IQ Protocol
- Execution of this IQ protocol
- Document Control of IQ Protocol until such document is completed, approved and after.
- Regulatory Compliance Review of the completed IQ Protocol
- Review and Approval of the executed IQ Protocol.

5.0 SYSTEM DESCRIPTIONS

In this equipment High Speed sealing Machine is versatile self supported on stainless steel legs with height adjustable adjustment system. The machine is precision made on sturdy welded stainless steel frame and completely enclosed in stainless steel covers. Doors are provided to facilitate the servicing of m/c. The table top plate is made from good quality steel and claded with stainless steel. The bottles travelling on the infeed side of the conveyor are separated by the feed worm and fed to the infeed turret. The infeed turret transfer bottles to the central turret. The bottle transferred on the central turret so as to seal and threading. The frequency can be varied from the control panel and the amplitude can be varied adjusting the eccentricity. Cap is coming from the orienter and comes on cap chute .The bottle pick up the cap transferred on the central turret so as to seal and threading the cap.

6.0 DOCUMENTATION REQUIREMENTS (Ref:)

The IQ File should include:

- This IQ Protocol
- All printouts and handouts generated during qualification procedure
- A Signature Sheet where all people, performing the qualification checks, are listed
- Any change control actions that may have occurred during the qualification activities.
- Any deviations, exceptions or investigation reports generated during the qualification activities.

7.0 DATA COLLECTION

All individuals executing this Protocol shall complete the *Signature Sheet* .All personnel shall have suitable documented training or experience.

All approvals shall be made in BLACK ink.
All data entry shall be made in BLACK ink.

All corrections to this Protocol, which are not retyped, are to be made in *BLACK* ink. All written corrections to this Protocol or to data entered in this Protocol should be made by using a single line to delete the error. The person who makes the correction shall initial and date it and add comment to explain reason for correction.
After performing the checks, collect all relevant printouts and certificates and retain for inclusion in the IQ File. If more Data Sheets or Deviation Sheets are required, they are to be attached to this Protocol as *Annexures* and to be listed in *Section 13. List of Annexures*.

8.0 CHANGE CONTROL

Any changes or modifications to the system shall be performed in accordance with the Change Control Procedure.

Change Control Forms raised during the execution of this IQ will be filed with the protocol. An assessment will be made to check whether any re-validation is required before the change request is closed out.

9.0 PRE-QUALIFICATION REQUIREMENTS

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to IQ commencing. Open action items resulting from these tests shall be listed in the Comments section.

Test	Test Date	Documentation [Title, Rev.]	Documentation Location	Complete [Y/N]	Initial / Date

FAT					
Commissioning					
SAT					

Comments:

Reviewed by		Date	

10.0 TESTS AND CHECKS

The following tests and checks are to be completed for IQ of ROPP Bottle sealing machine. After completion of this section, fill the *Checklist* in *Section 10*.

10.1 DRAWING VERIFICATION (REF:)

10.1.1 OBJECTIVE

To verify that relevant drawings of the equipment are available and current.

10.1.2 METHOD

Examine whether the specified drawings of equipment are available and current. Ensure Title, Revision No., Originator and Document Location are recorded in *Section 10.1.4 Data*. Record any deviation / non-conformance as described in *Section 12. Deviation Sheet.*

10.1.3 ACCEPTANCE CRITERIA

Drawings must be of the latest version approved and filed correctly.

10.1.4 DATA

Reference Engineering Drawings [Title, No., Originator (Company)]	Document Location	Acceptable [Y/N]	Initial / Date
GA Drawing of equipment			
Main Drive Gear Box assembly			

Comments:

Reviewed by		Date	

10.2 EQUIPMENT VERIFICATION (REF:)

10.2.1 OBJECTIVE

To verify that the equipment components are as specified.

10.2.2 METHOD

Visually examine all equipment components as listed in the tables below. Confirm that all specified requirements listed in SPECIFIED column [*Section 10.3.4. Data*] have been met. Record any deviations/non-conformances as described in *Section 12. Deviation Sheet*.

10.2.3 ACCEPTANCE CRITERIA

Equipment must be in conformance to specifications as listed in the SPECIFIED column in Section 10.3.4.

10.2.4 DATA

S.No.	Description	Actual	Initial/Date
1.	Verify that major components are securely anchored and shock proof		
2.	Verify that all-critical instruments have Identification tags.		
3.	Verify that there is no observable physical damage to the equipment.		
4.	Verify that there is sufficient room of servicing provided.		
5.	Required electrical connections are tight, weather proof and properly earthed.		

10.2.4.1 ROPP BOTTLE SEALING MACHINE

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL FOR BOTTLE SEALING MACHINE (ROPP CAP)	PROTOCOL No.:

Parameters	Specified	Actual	Acceptable [Y/N]	Initial/Date
Equipment Name	ROPP Bottle sealing machine			
Manufacturer	JP machine Tools			
Model/Type	cGMP Model			
Capacity	Max.240 bottles per min.			
Dimensions	2150L x 1100W x 2090mm(H)			
MOC Chute	SS 304			
Loading Arrangement	Orienter			

Comments:

Reviewed by		Date	

10.2.4.2 COMPONENTS OF MACHINE

Parameters	Specified	Actual	Acceptable [Y / N]	Initial / Date
Drive motor				
Manufacturer	HAVELLS			
HP	1			
RPM	1390			
Gearbox				
Make	BONFIGLIOLI			
Hz	15:1 ratio , FLANGE mounted			
Orienter geared motor				
Manufacturer	Bonfiglioli			
HP	0.125			
RPM	24			
Conveyor Gear motor				
Make	Bonfiglioli			
HP	0.25			
RPM	50			
Chute				
MOC	SS 304			
Covers & Panels				
MOC	SS 304			
Feed worm				
Make	Derlin			
Capping head assembly				
MOC	SS-304, Al. and plastics			
Star wheels				
MOC	UHMWPE			
Description	Rotating star wheels for movements of bottles			

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL FOR BOTTLE SEALING MACHINE (ROPP CAP)	PROTOCOL No.:

Parameters	Specified	Actual	Acceptable [Y / N]	Initial / Date
Cap feeder				
MOC	SS 304			
Feed worm				
MOC	Delrin			
Chute				
MOC	SS 304			
Proxy Switch and photo sensor.				
Specification	INDUCTIVE, Photo sensor:- PNP/NO Spec: PNP/NO			
Chute				
MOC	SS 304			
Conveyor chain				
MOC	Delrin			
Leveling bolt				
Make	m-16x100 long MOC-SS-304			

Comments:

Reviewed by		Date	

10.3 MATERIALS IN PRODUCT CONTACT (REF :)

10.3.1 OBJECTIVE

To verify that all materials in product contact meet the specified requirements.

10.3.2 METHOD

Examine there is documented evidence that all materials that come into product contact meet the required specifications for material type and surface finish as applicable. Attach documents/identify the location. Utilities (such as nitrogen, air, steam, water) that subsequently come into contact with the pharmaceutical products shall be deemed as "product". Report any deviation / non-conformances as described in Section 12. Deviation Sheet.

10.3.3 ACCEPTANCE CRITERIA

All materials in product contact must be in conformance with the specifications listed in the SPECIFIED column in Section 10.5.4. Data. Documented evidence attached/location checked.

10.3.4 DATA

System Component	Reference Document [Title, No., Rev. No., Date]	Specified	Actual	Material Certificate Available [Y/N, Location]	Acceptable [Y/N]	Initial / Date
Cam	Technical Specification of Screw cap machine	SG Iron				
Cam Follower		Standard Bearing				
Star wheel		UHMWPE				
Feed worm		Delrin				
Conveyor chain		Delrin				
Door frame		Aluminum				
Cap Orienter		SS-304, Polycarbonate, Aluminum				
Conveyor channels		SS-304				
Cap chute		SS-304				
CAPPING HEAD ASSY.		SS-304, Aluminum, Plastic				

Comments:

Reviewed by		Date	

10.4 SERVICES VERIFICATION (REF:)

10.4.1 OBJECTIVE

To verify that all services required for the operation of the system are available and connected to the system and that these utilities conform to the system requirement.

10.4.2 METHOD

Visually examine that all services are available and connected in accordance with the applicable engineering drawings and system specifications. Complete the list of services installed in *Section 9.6.4 Data*. Record any deviation / non-conformances as described in *Section 11. Deviation Sheet*.

10.4.3 ACCEPTANCE CRITERIA

All services are available and connected in conformance to specifications listed in the SPECIFIED column in Section 9.6.4 Data.

10.4.4 DATA

Electricity	• Voltage: 415V • Phases: 3 • Frequency: 50 Hz	• Voltage: • Phases: • Frequency:		

Comments:

Reviewed by		Date	

10.5 AUTOMATION AND CONTROL SYSTEMS HARDWARE INSTALLATION VERIFICATION (REF:)

10.5.1 OBJECTIVE

To verify that the control and monitoring devices are installed as specified.

10.5.2 METHOD

Visually examine the hardware components as listed in the SPECIFIED column in *Section 10.7.4. Data*.
Report any deviation / non-conformances as described in *Section 12. Deviation Sheet*.

10.5.3 ACCEPTANCE CRITERIA

The hardware components must be in conformance to the specifications listed in the SPECIFIED column.

10.5.4 DATA

10.5.4.1 PLC CONTROLLER

Parameters	Specified	Actual	Acceptable [Y / N]	Initial / Date
AC drive				
Manufacturer	DELTA			
Proximity Switches & Photocells				
Description	PNP, NO			
Pneumatic cylinders				
Make	SMC/Festo			
FRL unit				
Make	SMC/Festo			

Comments:

Reviewed by		Date	

10.5 SPARE PARTS LIST

10.5.5 OBJECTIVE

To verify the availability of specified spare part lists.

10.5.6 METHOD

Examine for the availability of spare part lists and attach either as *Annexure* or indicate location of the actual spare part lists. Record any deviations / non-conformances as described in Section 12 Deviation *Sheet*.

10.5.7 ACCEPTANCE CRITERIA

Approved spare part lists must be available.

10.5.8 DATA

Spare Parts List	Confirm Attached or Refer to Location	Initial / Date
General Spare Parts List		
Mechanical Spare Parts List		
Electrical Spare Parts List		

Comments:

Reviewed by		Date	

10.6 LUBRICANTS LIST

10.6.1 OBJECTIVE

To verify all fluids used in the system are as specified.

10.6.2 METHOD

Examine whether all fluids used in the system are as listed in the SPECIFIED column in *Section 10.9.4. Data*. Classify whether each fluid may be in product contact or not. Record the quantity and location of the fluids inventory. Confirm that all specified requirements have been met. Record any deviations / non-conformances as described in Section 12. Deviation Sheet.

10.6.3 ACCEPTANCE CRITERIA

Fluids used must be in conformance with the specifications listed in the SPECIFIED column.

10.6.4 LUBRICANT

Fluid	Product Contact [Y/N]	Specified	Actual	Quantity & Location of Inventory	Acceptable [Y / N]	Initial / Date
Enclo 68	Y	Enclo 68				
Omala 220	Y	Omala 220				

Comments:

Reviewed by		Date	

10.7 VISUAL INSPECTION

10.8.1 OBJECTIVE

To verify that the ROPP Bottle sealing Machine is ready for operation.

10.8.2 METHOD

Visually examine that the installation of Bottle sealing Machine (ROPP) is completed and that all instrument / component packaging is removed. Visually examine the cleanliness of the ROPP Bottle sealing Machine and verify that all connections to instrument/components (electrical wire, hoses, pipes, clamps, etc) are firmly affixed. Confirm that the ROPP Bottle sealing Machine is ready for operation.

10.8.3 ACCEPTANCE CRITERIA

The specifications listed in the SPECIFIED column are met.

10.8.4 DATA

S.No.	Specified	Acceptable [Y/N]	Initial / Date
1.	Installation of ROPP Bottle sealing Machine is completed.		
2.	ROPP Bottle sealing Machine is clean.		
3.	All instrument/component packaging is removed.		
4.	All instrument/ component Chute , orienter etc firmly affixed.		
5.	All accessories are available.		

Comments:

Reviewed by		Date	

11.0 CHECKLIST OF ALL TESTS AND CHECKS

This checklist is provided to ensure that all tests or checks required for this IQ have been executed.

Reference No.	Tests or Checks	Executed [Y/N]	Comment
	Drawing Verification		
	Equipment Verification		
	Instrumentation Verification		
	Materials in Product Contact		
	Services Verification		
	Spare Parts List		
	Lubricant List		
	Visual Inspection		

Comments:

Reviewed by		Date	

12.0 DEVIATION SHEET

Report any deviations from the acceptance criteria or exceptions from protocol instructions in the Record Sheet as described in SOP Handling of Deviations .Record the total number of exceptions / deviations reported during the qualification activities of this Protocol. Record the Deviation Number and Title in the Table below. Include all Deviation Record Sheets in the IQ File.

TOTAL NO. OF EXCEPTIONS / DEVIATIONS = _____

Exception / Deviation No.	Exception / Deviation Title	Status

Comments:

Reviewed by		Date	

12.1 DEVIATION AND CORRECTIVE ACTION REPORT FORM

This Deviation and Corrective Action Report Form shall be completed for each result that does not meet the

expected or as designed condition encountered during the execution of the protocol. Each form shall be numbered sequentially and tracked on the Deviation Sheet within the protocol.

Deviation Report Number:
Protocol Section No.: Date of Test:
Description Of Test Result:
Immediate Action Taken:
Corrective Action Taken / Planned:
Deviation Reported By: Name: Signature: Date:
Corrective action must be taken prior to approval of IQ or OQ? :
Head - Engg. Signature Date:
Head-User dept. signature Date
QA Signature: Date:
<u>Corrective Action Implemented:</u>
Corrective Action Implemented By: Name: Signature: Date:
(Attach comments and supporting documentation as necessary)
Was a re-test or amendment necessary due to the Deviation? Date of re-test:
Is Deviation Closed (Yes/No):
QA Signature: Date:

13.0 REFERENCES

The Principle Reference is the following

- Master Validation 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, General. 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.
- GAMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.
- SOP -"Handling of Deviations".
- SOP -"Change Control Procedure".

14.0 LIST OF ANNEXURES

Annexure No.	Document Title

15.0 SUMMARY:

16.0 APPROVALS

The following approvals signify that the IQ is complete and acceptable and that the system is ready for OQ Execution.

EXECUTED BY:

Department	Name	Designation	Signature	Date
Production				
Engg. Dept.				
QA Dept.				

REVIEWED BY:

Department	Name	Designation	Signature	Date
Production Dept.				
Engg. Dept.				
QA Dept.				

APPROVED BY:

Department	Name	Designation	Signature	Date
HEAD - QA				
Plant Head				