



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**INSTALLATION QUALIFICATION  
PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

<b>Equipment ID</b>	
<b>Equipment Location</b>	<b>Bottle loading room</b>
<b>Equipment Make</b>	<b>JP machine tools</b>
<b>Document No.</b>	
<b>Reason for Qualification</b>	<b>New Equipment</b>



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**TABLE CONTENT**

<b>Sr. No.</b>	<b>Description</b>	<b>Page No.</b>
<b>1.0</b>	<b>Preapproval</b>	<b>3</b>
<b>2.0</b>	<b>Objective</b>	<b>4</b>
<b>3.0</b>	<b>Scope</b>	<b>4</b>
<b>4.0</b>	<b>Responsibilities</b>	<b>4-5</b>
<b>5.0</b>	<b>System Description</b>	<b>5</b>
<b>5.1</b>	<b>Bottle loader machine</b>	<b>5</b>
<b>6.0</b>	<b>Documentation Requirements</b>	<b>5</b>
<b>7.0</b>	<b>Data Collection</b>	<b>5</b>
<b>8.0</b>	<b>Change Control</b>	<b>6</b>
<b>9.0</b>	<b>Pre-Qualification Requirements</b>	<b>6</b>
<b>10.0</b>	<b>Tests and Checks</b>	<b>7</b>
<b>10.1</b>	<b>Drawing verification</b>	<b>7</b>
<b>10.2</b>	<b>Equipment Verification</b>	<b>8-10</b>
<b>10.3</b>	<b>Material in product contact</b>	<b>11</b>
<b>10.4</b>	<b>Service verifiaction</b>	<b>12</b>
<b>10.5</b>	<b>Automation And Control</b>	<b>13</b>
<b>10.6</b>	<b>Spare part list</b>	<b>14</b>
<b>10.7</b>	<b>Lubrication Test</b>	<b>15</b>
<b>10.8</b>	<b>Visual inspection</b>	<b>16</b>
<b>11.0</b>	<b>Checklist of All Tests And Checks</b>	<b>17</b>
<b>12.0</b>	<b>Deviation Sheet</b>	<b>18-19</b>
<b>13.0</b>	<b>References</b>	<b>20</b>
<b>14.0</b>	<b>List of Annexures</b>	<b>21</b>
<b>15.0</b>	<b>Summary</b>	<b>22</b>
<b>16.0</b>	<b>Post Approvals</b>	<b>23</b>



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**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			



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**2.0 OBJECTIVES**

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

- To verify that the Bottle loader 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 Bottle loading machine serving the .....; Tablets, Capsules & Dry Syrup, Dry Powder injection and Oral Manufacturing Facility. Scope incorporates qualification of all Bottle loader Machine components such as plate, tooling components etc.

This protocol will define the methods and documentation used to qualify the Bottle loader Machine for IQ. Successful completion of this protocol will verify that the Bottle loader 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.



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**5.0 SYSTEM DESCRIPTIONS**

Very High Speed Bottle loader machine has following major components.

**5.1 Bottle loader machine**

Very High Speed Bottle loader machine is versatile self supported on stainless steel leg with height adjustable adjustment system. The machine is precision Equipment on sturdy welded steel frame completely enclose in stainless steel sheet and doors are provided to facilitate to servicing of m/c. The container moving on conveyor belt are separated by in feed worm and transferred to the infeed turret which then transfer it to the center turret below the cap sealing head. The caps are oriented in the cap orienter; the oriented caps are moved to the cap transfer turret thru' the cap chute. The cap sealing head, which is synchronized with the cap transfer turret, picks up the cap from the cap transfer turret. The cap sealing head comes down on the container and tightens the cap with pre set torque. Each cap sealing head is provided with an adjustable torque magnetic clutch. The clutch slips on reaching the adjusted torque. The capped container is then moved from center turret to the out feed turret and then on to the exit side of the conveyor.

**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 (SOP No.:.....).

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.



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**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.

<b>Test</b>	<b>Test Date</b>	<b>Documentation [Title, Rev.]</b>	<b>Documentation Location</b>	<b>Complete [Y/N]</b>	<b>Initial/Date</b>
FAT					
Commissioning					
SAT					

Comments:

Reviewed by		Date	
-------------	--	------	--



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**10.0 TESTS AND CHECKS**

The following tests and checks are to be completed for IQ of Bottle loader 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	
-------------	--	------	--



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**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.		





**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**10.2.4.1 BOTTLE LOADER MACHINE:**

<b>Parameters</b>	<b>Specified</b>	<b>Actual</b>	<b>Acceptable [Y/N]</b>	<b>Initial/Date</b>
Equipment Name	Bottle loader machine			
Manufacturer	JP machine Tools			
Model/Type	cGMP model			
Capacity	Max.240 bottles per min.			
Dimensions	1000x1100x1000 mm			
MOC of table	SS 304			

Comments:

Reviewed by

Date



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**10.2.4.2 COMPONENTS OF MACHINE**

Parameters	Specified	Actual	Acceptable [Y/N]	Initial/Date
<b>Drive motor</b>				
Manufacturer	HAVELLS			
HP	1			
RPM	1390			
<b>Gearbox</b>				
Make	BONFIGLIOLI			
Hz	15:1 ratio , FLANGE mounted			
<b>Covers &amp; Panels</b>				
MOC	SS 304			
<b>Pneumatic cylinder</b>				
Make	SMC, with Solenoid valves make:-SMC			

Comments:

Reviewed by		Date	
-------------	--	------	--



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**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
Table	Technical Specification of Screw cap machine	SS 304				
Guide		SS 304				

Comments:

Reviewed by

Date



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**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**

Services	Specified	Actual	Acceptable [Y/N]	Initial/Date
Compressed Air	<ul style="list-style-type: none"><li>• Pressure: 6 kg/cm<sup>2</sup> (g)</li><li>• Pipe Material: SS</li><li>• Quality: Oil, water &amp; dust free.</li><li>• Flow pressure : 4 kg/ cm<sup>2</sup></li></ul>	<ul style="list-style-type: none"><li>• Pressure:</li><li>• Pipe Material:</li><li>• Quality:</li><li>• Flow pressure:</li></ul>		

Comments:

Reviewed by		Date	
-------------	--	------	--



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**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
<b>Pneumatic cylinders</b>				
Make	SMC/Festo			

Comments:

Reviewed by		Date	
-------------	--	------	--



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**10.6 SPARE PARTS LIST**

**10.6.1 OBJECTIVE**

To verify the availability of specified spare part lists

**10.6.2 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*.

**10.6.3 ACCEPTANCE CRITERIA**

Approved spare part lists must be available.

**10.6.4 DATA**

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

Comments:

Reviewed by		Date	
-------------	--	------	--



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**10.7 LUBRICANTS LIST**

**10.7.1 OBJECTIVE**

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

**10.7.2 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.

**10.7.3 ACCEPTANCE CRITERIA**

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

**10.7.4 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	
-------------	--	------	--



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**10.8 VISUAL INSPECTION**

**10.8.1 OBJECTIVE**

To verify that the Bottle loader Machine is ready for operation.

**10.8.2 METHOD**

Visually examine that the installation of Bottle loader Machine is completed and that all instrument /component packaging is removed. Visually examine the cleanliness of the Bottle loader Machine and verify that all connections to instrument/components (electrical wire, hoses, pipes, clamps, etc) are firmly affixed. Confirm that the Bottle loader 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 Bottle loader Machine is completed.		
2.	Bottle loader Machine is clean.		
3.	All instrument/component packaging is removed.		
4.	All instrument/ component cylinder, solid oil valves etc firmly affixed.		
5.	All accessories are available.		

Comments:

Reviewed by

Date





**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**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
11.1	Drawing Verification		
11.2	Equipment Verification		
11.3	Instrumentation Verification		
11.4	Materials in Product Contact		
11.5	Services Verification		
11.6	Spare Parts List		
11.7	Lubricant List		
11.8	Visual Inspection		

Comments:

------------------

Reviewed by		Date	
-------------	--	------	--



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**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 = \_\_\_\_\_**

<b>Exception/Deviation No.</b>	<b>Exception/Deviation Title</b>	<b>Status</b>

Comments:

Reviewed by		Date	
-------------	--	------	--



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**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.

<b>Deviation Report Number:</b>		
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:	
<b><u>Corrective Action Implemented:</u></b>		
Corrective Action Implemented By:		
Name:	Signature:	Date:
<b>(Attach comments and supporting documentation as necessary)</b>		
Was a re-test or amendment necessary due to the Deviation?	Date of re-test:	
<b>Is Deviation Closed (Yes/No):</b>		
QA Signature:	Date:	



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**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”.







**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

**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				