



**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES  
WASHING, DRYING & SELF ADHESIVE  
LABELING MACHINE**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Packing Hall, Ampoules Line ‘</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



PHARMA DEVILS

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**PROTOCOL CONTENTS**

<b>S.No.</b>	<b>TITLE</b>	<b>PAGE No.</b>
<b>1.0</b>	<b>PROTOCOL PRE-APPROVAL</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>RESPONSIBILITY</b>	<b>5</b>
<b>5.0</b>	<b>EQUIPMENT DETAILS</b>	<b>6</b>
<b>6.0</b>	<b>EQUIPMENT DESCRIPTION</b>	<b>6</b>
<b>7.0</b>	<b>PRE-QUALIFICATION REQUIREMENTS</b>	<b>9</b>
<b>8.0</b>	<b>CRITICAL VARIABLES TO BE MET</b>	<b>10-16</b>
<b>9.0</b>	<b>REFERENCES</b>	<b>17</b>
<b>10.0</b>	<b>DOCUMENTS TO BE ATTACHED</b>	<b>17</b>
<b>11.0</b>	<b>DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY</b>	<b>17</b>
<b>12.0</b>	<b>CHANGE CONTROL, IF ANY</b>	<b>17</b>
<b>13.0</b>	<b>REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY)</b>	<b>18</b>
<b>14.0</b>	<b>CONCLUSION</b>	<b>18</b>
<b>15.0</b>	<b>RECOMMENDATION</b>	<b>18</b>
<b>16.0</b>	<b>ABBREVIATIONS</b>	<b>19</b>
<b>17.0</b>	<b>PROTOCOL POST- APPROVAL</b>	<b>20</b>



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**1.0 PROTOCOL PRE – APPROVAL:**

**INITIATED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			



**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**2.0 OBJECTIVE:**

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

**3.0 SCOPE:**

- The scope of this operational qualification protocol cum report is limited to qualification of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine (**Make:** Aseptic Technology Inc.) Installed in Packing Hall, Ampoules Line.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine.
- Successful completion of this Protocol will verify that Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine meet all acceptance criteria and ready for Performance Qualification.



**OPERATIONAL QUALIFICATION  
 PROTOCOL CUM REPORT  
 FOR  
 AUTOMATIC EXTERNAL AMPOULES WASHING,  
 DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**4.0 RESPONSIBILITY:**

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
<b>Quality Assurance</b>	<ul style="list-style-type: none"> <li>• Preparation, Review, Approval and compilation of the operational Qualification Protocol cum Report.</li> <li>• Co-ordination with Production and Engineering to carryout Operational Qualification.</li> <li>• Monitoring of Operation Process.</li> <li>• Post approval of Operational Qualification Protocol cum Report after execution.</li> </ul>
<b>Production</b>	<ul style="list-style-type: none"> <li>• Review &amp; Pre Approval of Operational Qualification Protocol cum Report.</li> <li>• To Co-ordinate and support for execution of Operational Qualification study as per Protocol.</li> <li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li> </ul>
<b>Engineering</b>	<ul style="list-style-type: none"> <li>• Review &amp; Pre Approval of Operational Qualification Protocol cum Report.</li> <li>• To co-ordinate and support Operational Qualification Activity..</li> <li>• Post approval of Operational Qualification Protocol cum Report after execution.</li> </ul>



**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine
<b>Equipment ID.</b>	
<b>Manufacturer's Name</b>	Aseptic Technology inc.
<b>Machine No.</b>	
<b>Model No.</b>	EWL-400
<b>Supplier's Name</b>	Aseptic Technology inc.
<b>Location of Installation</b>	Packing Hall, Ampoules line

**6.0 EQUIPEMENT DESCRIPTION:**

**INFEEED TRAY**

This machine is equipped with In-feed Tray system for loading of Ampoules. The Ampoules are loaded into the SS Tray and from this tray the Ampoules are passed to the In-feed Feed worm.

**STAR WHEEL ASSEMBLY**

A star wheel is made of Aluminum casting material. Star wheel is transfer the Ampoule one by one for washing and drying.

**TANK ASSEMBLY**

This machine is equipped with of SS304 Tank for Re- Circulated Water. And one for Purified water According to the washing cycle the piping are provided. Along with the Tanks Grundfoss Pumps & Require Heating arrangement are provided.

Purified water received from Loop is used for Final washing and this water collected into Re cycle Tank. This re cycle water is filtered through suitable Filtration system and again used for washing at First station and finally washed water goes to Drain.

**AIR KNIFE ASSEMBLY**

Air knife is made of Aluminum material with black anodizing. Air Knife is blowing the dry air on Ampoule for Drying the Ampoule. Also the machine is equipped with Blower. This is connected at the out-feed end after the washing is over. This ensures that proper drying takes place as the machine is running at the high speed.



**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**OUT FEED FEEDWORM ASSEMBLY**

Out feed worm is made of Delrin material. Feed worm is feed the Ampoule One by one in collection tray.

**LABEL DISPENSING DEVICE**

It works on the basic principle of to apply sticker label on Ampoule, which is previously sensed by the Ampoule sensor, after getting the signal from the Ampoule sensor, it allows the label to come out from the label roll up to the label length which is feed in the HMI Unit of the machine. And label sensor sense the gap between the two labels and allows only single label to come out. The control of label dispensing device is on Servo Motor, Servo Drive, Ampoule Sensor and label Sensor.

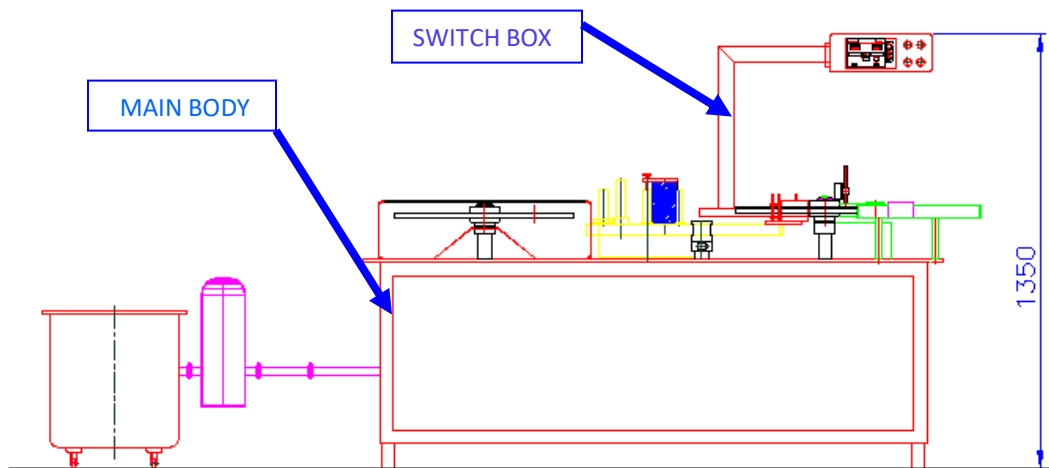
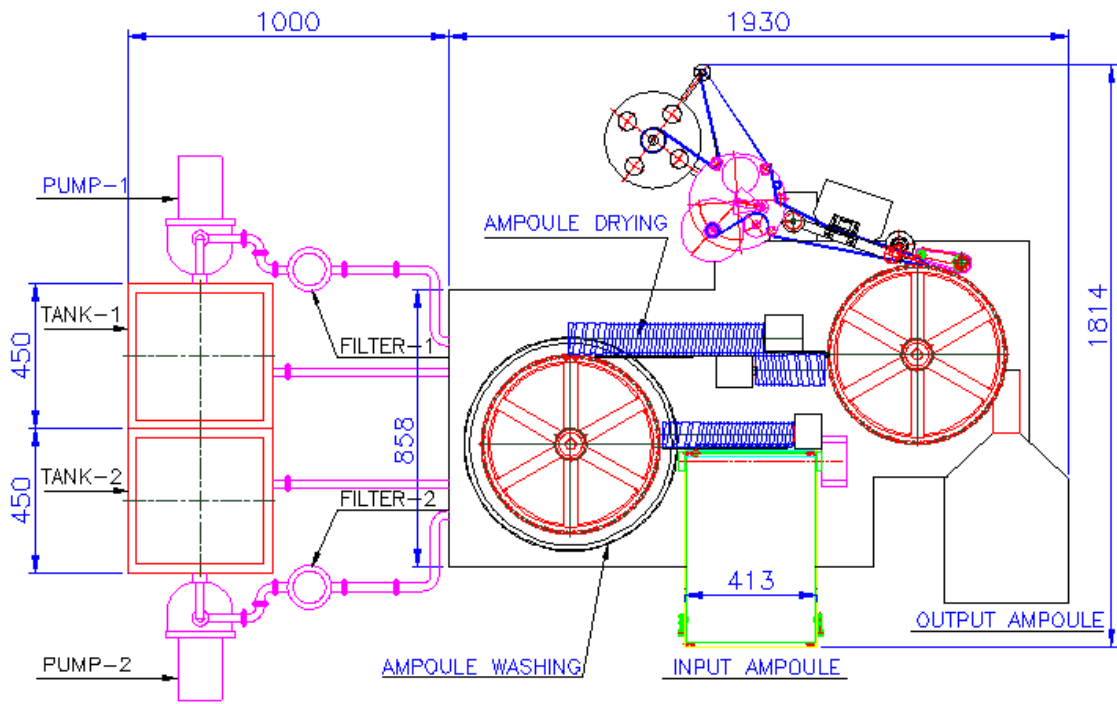
**PRESSING DEVICE**

It works on the basic Principle to press the sticker label on the Ampoule, which is previously applied by the label dispensing device. When sticker label is applied the applicator simultaneously Ampoule enters in to the pressing belt assembly and it will start move in rotary motion between the pressing belt and pressing pad. This allows the label to stick firmly on Ampoule and resulting wrinkle free Labeling.



**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**



**GA of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine:**





**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**7.0 PRE - QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation & Cleaning of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine.
- Draft SOP for Preventive Maintenance of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine.

**7.1.1 Procedure:**

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum Report.

**7.1.2 Acceptance Criteria:**

All the documents should be available, complete and approved by respective authorities.



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 Verification of documents:**

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 OQ commencing.

S.No.	DOCUMENT NAME	DOCUMENT / SOP No.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE
1.	DQ Protocol cum Report			
2.	IQ Protocol cum Report			
3.	Draft SOP for Operation & Cleaning of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine.			
4.	Draft SOP for Preventive Maintenance of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine.			

**Checked By (Production)**  
Sign/Date: .....

**Verified By (Quality Assurance)**  
Sign/Date: .....

**Inference:**

.....  
.....  
.....  
.....

**Reviewed By (Manager QA)**  
Sign/Date: .....



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**8.2 Functional Checks:**

Operate the Automatic External Ampoules Washing, Drying & Self\_Adhesive Labeling Machine as per Manufacturer’s Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

<b>FUNCTIONAL CHECK</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATIONS</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
Main ON/ Key switch.	To Connect/ disconnect the power supply to the control panel /machine.		
All Function key or Touch key from HMI	As stated in related operating manual.		
Emergency stop push button.	To stop machine in emergency.		
Turn the Knob for desired speed.	Speed will Increase / Decrease.		

**Checked By  
(Production)  
Sign/Date: .....**

**Verified By  
(Quality Assurance)  
Sign/Date: .....**

**Inference:**

.....

.....

.....

.....

**Reviewed By  
(Manager QA)  
Sign/Date: .....**



**OPERATIONAL QUALIFICATION  
 PROTOCOL CUM REPORT  
 FOR  
 AUTOMATIC EXTERNAL AMPOULES WASHING,  
 DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**8.3 Safety Features, Alarms & Interlock:** The equipment shall be provided with safety features as listed below.

<b>TEST</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
No Ampoule No Labeling.	No Ampoule No Labeling System is provided while machine is running in ideal condition and Ampoule is not present on Star Wheel.		
Emergency Stop	Machine stop		
Re. Cir. Temperature Low	Machine Stop		
Re. Cir. Water Pressure Low	Machine Stop		
Re. Cir. Tank Water Level Low	Machine Stop		
P.W. Temperature Low	Machine Stop		
P.W. Water Pressure Low	Machine Stop		
P.W. Tank Water Level Low	Machine Stop		
Guard Open (Washing Zone)	Machine Stop		
Pump Trip	Machine Stop		
Blower Trip	Machine Stop		
Main Star wheel Drive Trip	Machine Stop		
Air Pressure Low	Machine Stop		
Servo Drive Fault	Machine Stop		

**Checked By  
(Production)  
Sign/Date: .....**

**Verified By  
(Quality Assurance)  
Sign/Date: .....**

**Inference:**  
 .....  
 .....  
 .....  
 .....

**Reviewed By  
(Manager QA)  
Sign/Date: .....**



**OPERATIONAL QUALIFICATION  
 PROTOCOL CUM REPORT  
 FOR  
 AUTOMATIC EXTERNAL AMPOULES WASHING,  
 DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**8.4 Equipment in Auto mode:** Operate the Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine as per Manufacturer’s Manual/SOP in Auto mode and Check for the following System Setting Test of the Equipment.

SYSTEM SETTING	SATISFIED / NOT SATISFIED
System start up is OK	
AUTO Mode entry is ok	
AUTO Mode entry is ok	
AUTO Mode Setting is ok	
All Interlock is clear /OK	

**8.5 Servo Tuning:**

DESCRIPTION	SATISFIED / NOT SATISFIED
Enter in auto mode	
Change Value in field Name: Servo tuning and observe respective change in optional as mentioned in description.	
Change value of ACC. & DEC and observe respective change in operation as mentioned in description.	

**8.6 System Test:**

DESCRIPTION	SATISFIED / NOT SATISFIED
Access to all screen and touch keys	
Test can be Completed successfully	
Actual result = Result are the displayed on auto mode screen (Total label per minute)	

**Checked By  
 (Production)  
 Sign/Date:.....**

**Verified By  
 (Quality Assurance)  
 Sign/Date:.....**

**Inference:**

.....  
 .....  
 .....  
 .....

**Reviewed By  
 (Manager QA)  
 Sign/Date:.....**



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**8.7 Emergency Operation Verification:**

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
<b>ON/OFF Push button</b> <ul style="list-style-type: none"> <li>• <b>Press Stop Push Button</b></li> <li>• <b>Release ON Push Button</b></li> </ul>	Equipment should Stop		
	Equipment should Start		
<b>With the OFF button Pressed in, Try to cause movement of an Operating function.</b>	The Equipment will be inoperative.		

**Checked By  
(Production)  
Sign/Date: .....**

**Verified By  
(Quality Assurance)  
Sign/Date:.....**

**Inference:**

.....

.....

.....

.....

**Reviewed By  
(Manager QA)  
Sign/Date:.....**



**OPERATIONAL QUALIFICATION  
 PROTOCOL CUM REPORT  
 FOR  
 AUTOMATIC EXTERNAL AMPOULES WASHING,  
 DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**8.8 Trouble Shooting:** All trouble shooting , repair and maintenance procedure should be performed by qualified personnel only.

<b>PROBLUM</b>	<b>CAUSE</b>	<b>SOLUTION</b>	<b>SOLVE BY (ENGINEERING) (SIGN/DATE)</b>
<b>Motor Does not run (for any AC drive or Motor fault)</b>	MCB Tripped		
	AC Drive Tripped		
	Loose Wire		
	Bearing Jammed		
<b>Container not feeding Properly</b>	Sticky Conveyor		
	Wrong speed		
	Excess Pressure in Container feeder		
	Rail too Tight		
<b>Cross Labeling</b>	Applicator setting sensor setting		
	Sensor setting		
	Excess Pressure from the massage belt		

**Checked By  
(Production)**  
**Sign/Date:** .....

**Verified By  
(Quality Assurance)**  
**Sign/Date:** .....

**Inference:**  
 .....  
 .....  
 .....

**Reviewed By  
(Manager QA)**  
**Sign/Date:**.....



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**8.9 Power Failure Verification:**

<b>ITEM</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
<b>Power up after power Failure</b>	Machine should not start automatically with power.		
<b>Main Power Restored</b>	Equipment can be restarted with no problems or adverse conditions by Pressing start button.		
<b>Timer Check</b>	Time during Process should hold same as on power lost.		

**Checked By  
(Production)  
Sign/Date: .....**

**Verified By  
(Quality Assurance)  
Sign/Date: .....**

**Inference:**

.....

.....

.....

.....

**Reviewed By  
(Manager QA)  
Sign/Date:.....**





**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**9.0 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.

**10.0 DOCUMENTS TO BE ATTACHED:**

- Operation and Maintenance Manual.
- Any other Relevant Documents.

**11.0 DEVIATION FROM PREDEFINED SPECIFICATION, IF ANY:**

.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....

**12.0 CHANGE CONTROL, IF ANY:**

.....  
.....  
.....  
.....  
.....  
.....  
.....



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

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

.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....

**14.0 CONCLUSION:**

.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....

**15.0 RECOMMENDATION:**

.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**16.0 ABBREVIATIONS:**

cGMP : Current Good Manufacturing Practices

DQ : Design Qualification

HP : Horse Power

ID. : Identification

IQ : Installation Qualification

Kg : Kilo Gram

KW : Kilo Watt

mm : Millimetre

No. : Number

OQ : Operational Qualification

SOP : Standard Operating Procedure

WHO : World Health Organization



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**17.0 PROTOCOL POST- APPROVAL:**

**INITIATED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			