



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**PERFORMANCE QUALIFICATION  
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>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**REPORT CONTENTS**

<b>S.NO.</b>	<b>TITLE</b>	<b>PAGE NO.</b>
<b>1.0</b>	<b>REPORT 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>PRE-QUALIFICATION REQUIREMENT</b>	<b>6</b>
<b>7.0</b>	<b>TESTS &amp; CHECKS</b>	<b>7-17</b>
<b>8.0</b>	<b>CHECKLIST OF ALL TESTS AND CHECKS</b>	<b>18</b>
<b>9.0</b>	<b>DOCUMENTS TO BE ATTACHED</b>	<b>19</b>
<b>10.0</b>	<b>NON COMPLIANCE</b>	<b>19</b>
<b>11.0</b>	<b>DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY</b>	<b>19</b>
<b>12.0</b>	<b>CHANGE CONTROL, IF ANY</b>	<b>19</b>
<b>13.0</b>	<b>REVIEW INCLUSIVE OF FOLLOW UP ACTION, IF ANY</b>	<b>20</b>
<b>14.0</b>	<b>CONCLUSION</b>	<b>20</b>
<b>15.0</b>	<b>RECOMMENDATIONS</b>	<b>20</b>
<b>16.0</b>	<b>ABBREVIATIONS</b>	<b>21</b>
<b>17.0</b>	<b>REPORT POST APPROVAL</b>	<b>22</b>



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**1.0 REPORT 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>			



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**2.0 OBJECTIVE:**

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

**3.0 SCOPE:**

- The Protocol covers all aspects of Performance Qualification for the Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine (**Make:** Aseptic Technology inc.) installed in Packing Hall, Ampoules line.
- This Protocol will define the methods and documentation used to qualify the Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine for PQ.



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
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 execution of Performance Qualification Report.

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Approval and Compilation of the Performance Qualification Report.</li><li>• Co-ordination with, Production and Engineering to carryout Performance Qualification Activity.</li><li>• Monitoring of Performance Qualification Activity.</li><li>• Post approval of Performance Qualification Report after execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Performance Qualification Report.</li><li>• To co-ordinate and support Performance Qualification Activity.</li><li>• Post approval of Performance Qualification Report after execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Performance qualification Report for correctness, completeness and technical excellence.</li><li>• Responsible for trouble shooting (if occurred during execution).</li><li>• Maintenance &amp; preventive maintenance as per schedule.</li><li>• Post approval of Performance Qualification Report after execution.</li></ul>



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
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 PRE – QUALIFICATION REQUIREMENTS:**

Verification for availability, Completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- Executed and approved Design Qualification document
- Executed and approved Installation Qualification document
- Executed and approved Operational Qualification document
- SOP for operation & Cleaning of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine.
- SOP for Preventive Maintenance of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine.



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**7.0 TESTS AND CHECKS:**

**7.1 Verification of Documents:**

Record the observations for documents in the below mentioned table:

S.No.	DOCUMENT NAME	DOCUMENT / SOP No.	COMPLETED (YES/NO)	CHECKED BY (PRODUCTION) SIGN/DATE	VERIFIED BY (QA) SIGN/DATE
1.	Executed and approved Design Qualification Protocol Cum Report.				
2.	Executed and approved Installation Qualification Protocol cum Report.				
3.	Executed and approved Operational Qualification Protocol cum Report.				
4.	PQ Protocol approved				
5.	SOP for Operation & Cleaning of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine.				
6.	SOP for Preventive Maintenance of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine.				

**Inference:**

.....

.....

.....

.....

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



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**7.2 TEST PRODUCT BATCH INFORMATION:**

S.No.	PRODUCT NAME	BATCH NO.	PACK SIZE	BATCH SIZE	MFG. DATE	EXPIRY DATE

**Compiled By  
(QA)**

**Sign/Date:.....**

**Inference:**

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

**Reviewed By  
(Manager QA)**

**Sign/Date:.....**





**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**7.3 REPORT OF PERFORMANCE EVALUATION USING DRUG PRODUCT:**

**(A) First Product Name: -**

**Batch No.:**

TEST & CHECK	SATISFIED / NOT SATISFIED
<b>Performance Verification Test</b>	
Auto mode setting is OK	
Stop watch is Ready	
Set machine speed 250 Ampoules per Minute	
After 1 min Machine speed (Amp/ Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 2 min Machine speed (Amp/ Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 3 min Machine speed (Amp/ Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 4 min Machine speed (Amp/ Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 5 min Machine speed (Amp/ Minute ) Total Count: Set :..... Display :..... Actual :.....	



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

TEST & CHECK	SATISFIED / NOT SATISFIED
Stop watch is Ready	
Set machine speed 300 Ampoules per Minute	
After 1 min Machine speed (Amp/ Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 2 min Machine speed (Amp/ Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 3 min Machine speed (Amp/ Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 4 min Machine speed (Amp/ Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 5 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	

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

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

**Inference:**

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

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



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

TEST	OBSERVATION
<b>Performance Evaluation Test</b>	
External Washing Quality	
External Drying	
Labeling Orientation	
Coding Imprint	
Positioning of Label	
Adhesiveness properties of label	
Shrinkage of label	
Dent / Rubbing mark on Label	
Affixing of labels edges	
Overlapping of Label	

**Acceptance criteria :**

**External Washing Quality :** Should be Clean

**External Drying :** Should be Dry

**Labeling Orientation :** Should be Uniform

**Coding Imprint :** Clear & legible

**Positioning of Label :** Should be proper and should not be tilted

**Adhesiveness properties of label :** Label should be properly Adhered to Ampoules

**Shrinkage of label :** Should be absent

**Dent /Rubbing mark on Label :** Should be absent

**Affixing of labels edges :** Label should be intact and properly fixed

**Overlapping of Label :** Should be absent

**Checked By  
(Production)**

**Sign/Date:**.....

**Verified By**

**(Quality Assurance)**

**Sign/ Date:**.....

**Inference:**

.....

.....

.....

.....

.....

**Reviewed By**

**(Manager QA)**

**Sign / Date:**.....



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**(B) Second Product Name: -**

**Batch No.:**

TEST & CHECK	SATISFIED / NOT SATISFIED
<b>Performance Verification Test</b>	
Auto mode setting is OK	
Stop watch is Ready	
Set machine speed 250 Ampoules per Minute	
After 1 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 2 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 3 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 4 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 5 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

TEST & CHECK	SATISFIED / NOT SATISFIED
Stop watch is Ready	
Set machine speed 300 Ampoules per Minute	
After 1 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 2 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 3 min Machine speed (Amp / Minute) Total Count: Set :..... Display :..... Actual :.....	
After 4 min Machine speed (Amp / Minute) Total Count: Set :..... Display :..... Actual :.....	
After 5 min Machine speed (Amp / Minute) Total Count: Set :..... Display :..... Actual :.....	

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

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

**Inference:**

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

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



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

TEST	OBSERVATION
<b>Performance Evaluation Test</b>	
External Washing Quality	
External Drying	
Labeling Orientation	
Coding Imprint	
Positioning of Label	
Adhesiveness properties of label	
Shrinkage of label	
Dent /Rubbing mark on Label	
Affixing of labels edges	
Overlapping of Label	

**Acceptance criteria :**

**External Washing Quality :** Should be Clean

**External Drying :** Should be Dry

**Labeling Orientation :** Should be Uniform

**Coding Imprint :** Clear & legible

**Positioning of Label :** Should be proper and should not be tilted

**Adhesiveness properties of label:** Label should be properly Adhered to Ampoules

**Shrinkage of label :** Should be absent

**Dent /Rubbing mark on Label :** Should be absent

**Affixing of labels edges :** Label should be intact and properly fixed

**Overlapping of Label :** Should be absent

**Checked By**

**(Production)**

**Sign/Date:**.....

**Verified By**

**(Quality Assurance)**

**Sign/Date:**.....

**Inference:**

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

**Reviewed By**

**(Manager QA)**

**Sign/Date:**.....



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**(C) Third Product Name:**

**Batch No.:**

TEST & CHECK	SATISFIED / NOT SATISFIED
<b>Performance Verification Test</b>	
Auto mode setting is OK	
Stop watch is Ready	
Set machine speed 250 Ampoules per Minute	
After 1 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 2 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 3 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 4 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 5 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

TEST & CHECK	SATISFIED / NOT SATISFIED
Stop watch is Ready	
Set machine speed 300 Ampoules per Minute	
After 1 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 2 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 3 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 4 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	
After 5 min Machine speed (Amp / Minute ) Total Count: Set :..... Display :..... Actual :.....	

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

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

**Inference:**

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

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





**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

TEST	OBSERVATION
<b>Performance Evaluation Test</b>	
External Washing Quality	
External Drying	
Labeling Orientation	
Coding Imprint	
Positioning of Label	
Adhesiveness properties of label	
Shrinkage of label	
Dent / Rubbing mark on Label	
Affixing of labels edges	
Overlapping of Label	

**Acceptance criteria :**

**External Washing Quality :** Should be Clean

**External Drying :** Should be Dry

**Labeling Orientation :** Should be Uniform

**Coding Imprint :** Clear & legible

**Positioning of Label :** Should be proper and should not be tilted

**Adhesiveness properties of label :** Label should be properly Adhered to Ampoules

**Shrinkage of label :** Should be absent

**Dent / Rubbing mark on Label :** Should be absent

**Affixing of labels edges :** Label should be intact and properly fixed

**Overlapping of Label :** Should be absent

**Checked By**

**(Production)**

**Sign/Date:**.....

**Verified By**

**(Quality Assurance)**

**Sign/Date:**.....

**Inference:**

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

**Reviewed By**

**(Manager QA)**

**Sign/Date:**.....



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**8.0 CHECKLIST OF ALL TESTS & CHECKS:**

This checklist is provided to ensure that all tests or checks required in Performance Qualification protocol have been executed.

TESTS OR CHECKS	EXECUTED (YES/NO)	REMARKS
Verification of DQ, IQ & OQ & other documents		
Verification of Performance using three batches of Products.		
Evaluation of Performance Using three batches of Products.		

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

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

**Inference:**

.....

.....

.....

.....

.....

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



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**9.0 DOCUMENTS TO BE ATTACHED:**

- Any Other Relevant Documents.

**10.0 NON COMPLIANCE:**

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

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

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

**12.0 CHANGE CONTROL , IF ANY:**

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



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
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**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**16.0 ABBREVIATIONS:**

ALM	:	Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine.
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
HMI	:	Human Machine Interface
IQ	:	Installation Qualification
LTD.	:	Limited
No.	:	Number
OQ	:	Operational Qualification
PPQ	:	Performance Qualification Protocol
PVT	:	Private
QA	:	Quality Assurance
RPQ	:	Performance Qualification Report
SOP	:	Standard Operating Procedure



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**17.0 REPORT 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>			