



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

PROTOCOL No.:

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

EQUIPMENT ID. No.	
LOCATION	Packing Hall, Ampoules Line
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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1.0 PROTOCOL 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)			



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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.



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4.0 RESPONSIBILITY:

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

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



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5.0 EQUIPMENT DETAILS:

Equipment Name	Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine
Equipment ID.	
Manufacturer's Name	Aseptic Technology inc.
Machine No.	EW-501/04/15-16
Model No.	EWL-400
Supplier's Name	Aseptic Technology inc.
Location of Installation	Packing Hall, Ampoules line

6.0 SYSTEM 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



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running at the high speed.

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

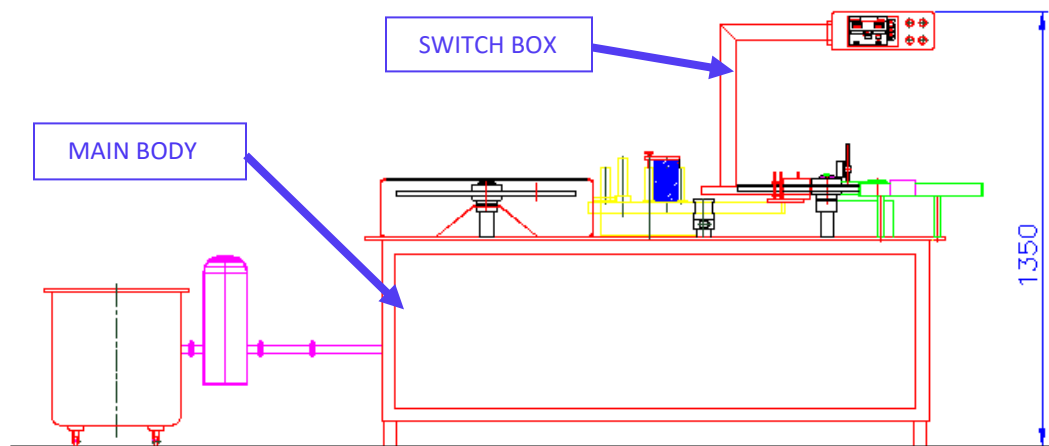
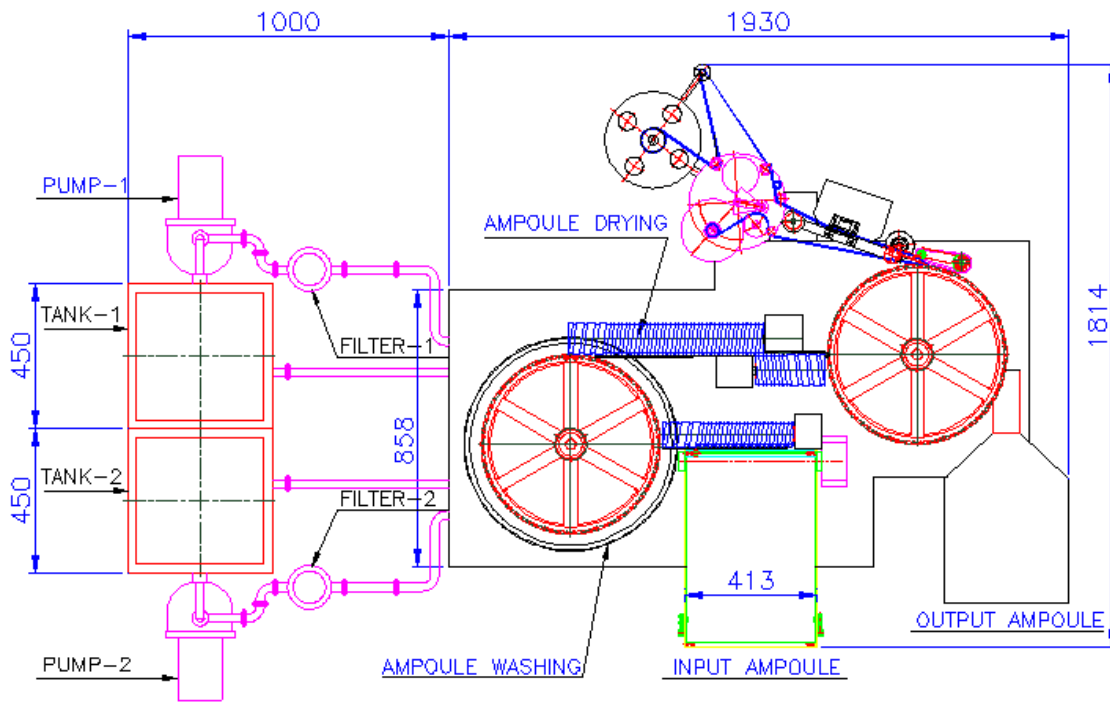
It works on the basic Principle to press the sticker label on the Ampoule, which is previously applied by the label dispensing device. When sticker label is applied the applicator simultaneously Ampoule enters in to the pressing belt assembly and it will start move in rotary motion between the pressing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



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



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7.0 REASON FOR QUALIFICATION:

- New equipment in Packing hall, Ampoules Line.
- After completion of the Operational Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

Packing hall, Ampoules Line.

9.0 FREQUENCY OF QUALIFICATION:

- After any major breakdown or after major modification.
- After Change of Location.
- Once in Two year

10.0 PRE – QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification
- Installation Qualification
- Operational Qualification
- 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.



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11.0 TESTS AND CHECKS:

11.1 Verification of Documents:

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.

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.
- Supporting documents would form a part of the PQ report.

Acceptance Criteria:

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



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11.2 Evaluation of Performance Using three batches of Products:

Objective:

- To verify the performance of equipment in the range of operational parameters established in Operational Qualification Activity.
- To establish documented evidence that Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine is performing consistently and the result of all test parameters meet the pre – defined acceptance criteria of sifted products.

11.2.1 Checks:

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



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TEST & CHECK	ACCEPTANCE CRITERIA
Stop watch is Ready	Should be Satisfied
Set machine speed 300 Ampoules per Minute	Should be Satisfied
After 1 min Machine speed (Amp/ Minute) Total Count: Set :..... Display :..... Actual :.....	Should be Satisfied
After 2 min Machine speed (Amp/ Minute) Total Count: Set :..... Display :..... Actual :.....	Should be Satisfied
After 3 min Machine speed (Amp/ Minute) Total Count: Set :..... Display :..... Actual :.....	Should be Satisfied
After 4 min Machine speed (Amp/ Minute) Total Count: Set :..... Display :..... Actual :.....	Should be Satisfied
After 5 min Machine speed (Amp / Minute) Total Count: Set :..... Display :..... Actual :.....	Should be Satisfied



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TEST	ACCEPTANCE CRITERIA
Performance Evaluation Test	
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

11.2.2 Method:

- Install product specific change parts and foil in the machine.
- Load the product in the hopper of machine
- Perform packing of product using machine as per the product specific parameters of the machine.
- Perform checks on the packed.
- Record the observations for all the checks in the report.

12.0 CHECKLIST OF ALL TESTS AND CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of DQ, IQ & OQ & other documents.
- Verification of performance using three batch of product.
- Evaluation of performance using three batch of product.



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13.0 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.

14.0 DOCUMENTS TO BE ATTACHED:

- Any other Relevant Document.

15.0 NON COMPLIANCE:

- All the Non-compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.



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18.0 ABBREVIATIONS:

ALM : Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine.

Asst. : Assistant

cGMP : Current Good Manufacturing Practices

DQ : Design Qualification

HMI : Humen Machine Interface

IQ : Installation Qualification

mm : Millimetre

No. : Number

OQ : Operational Qualification

PPQ : Performance Qualification Protocol

PQ : Performance Qualification

QA : Quality Assurance

SOP : Standard Operation Procedure

SS : Stainless Steel

WHO : World Health Organization