



**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOTTLE WASHING MACHINE**

PROTOCOL No.:

**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOTTLE WASHING MACHINE**

EQUIPMENT ID. No.	
LOCATION	Washing Room
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOTTLE WASHING MACHINE**

PROTOCOL No.:

CONTENTS

S.No.	TITLE	PAGE No.
1.0	Protocol Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment Details	6
6.0	System Description	6
7.0	Pre-Qualification Requirements	7
8.0	Critical Variables to be Met	8
9.0	References	10
10.0	Documents to be Attached	10
11.0	Deviation from Pre-Defined Specification, If Any	11
12.0	Change Control, If Any	11
13.0	Review (Inclusive of follow up action, If Any)	11
14.0	Conclusion	11
15.0	Recommendation	11
16.0	Abbreviations	12
17.0	Protocol Post Approval	13



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOTTLE WASHING MACHINE**

PROTOCOL No.:

1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOTTLE WASHING 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 Bottle Washing 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 Bottle Washing Machine (**Make**) installed in the Washing Room.
- This Protocol will define the methods and documentation used to perform OQ activity of Bottle Washing Machine for OQ.
- Successful completion of this Protocol will verify that Bottle Washing Machine meet all acceptance criteria and ready for Performance Qualification.



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOTTLE WASHING 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
Quality Assurance	<ul style="list-style-type: none">• Preparation, Review, Authorization and compilation of the operational Qualification protocol cum Report.• Co-ordination with Production and Engineering to carryout Operational Qualification.• Monitoring of Operation Process.• Post Approval of Operational Qualification Protocol cum Report after Execution
Production	<ul style="list-style-type: none">• Review & Approval of Operational Qualification Protocol cum Report.• To Co-ordinate and support for execution of Operational Qualification study as per Protocol.• Execution & Review of operational qualification protocol cum report.
Engineering	<ul style="list-style-type: none">• Review of Operational Qualification.• To co-ordinate and support Operational Qualification Activity.• Calibration of Process Instruments.• Post Approval of Operational Qualification Protocol cum Report after Execution



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOTTLE WASHING MACHINE**

PROTOCOL No.:

5.0 EQUIPMENT DETAILS:

Equipment Name	Bottle Washing Machine
Equipment ID	
Manufacturer's Name	
Model	
Supplier's Name	
Location of Installation	Washing Room

6.0 EQUIPEMENT DESCRIPTION:

The Bottle Washing Machine finishes the procedures from bottle in feed, cleaning, external precision cleaning, internal precision cleaning, and bottle out feed. It adopts the ultrasonic cleaning, uses the recycled water and compressed air to clean the internal and external of bottles by a series of nozzles.

The washing machine consists of the following parts, such as

1. Water Tank -02 Nos.
2. Pump-02 Nos.
3. Control Panel
4. Indexing mechanism
5. Flow Control valve & Distribution Pipe lines

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation and Cleaning of BOTTLE WASHING MACHINE.
- Draft SOP for Preventive Maintenance of BOTTLE WASHING MACHINE.
- Electrical circuits diagram.
- Technical specification of equipment.

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.



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOTTLE WASHING MACHINE**

PROTOCOL No.:

7.1.2 Acceptance Criteria:

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

S.No.	Document Name	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	DQ Protocol cum Report			
2.	IQ Protocol cum Report			
3.	Draft SOP for Operation & Cleaning of BOTTLE WASHING MACHINE			
4.	Draft SOP for Preventive Maintenance of BOTTLE WASHING 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
BOTTLE WASHING MACHINE**

PROTOCOL No.:

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Test Equipment Calibration:

Equipment / Instruments Name	Equipment/Instrument ID	Calibration On	Due On	Observed By Sign/Date

**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
 BOTTLE WASHING MACHINE**

PROTOCOL No.:

8.2 Operational & Functional Checks:

Component	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Switch with Key	Power ON & Power (Green) Indicator will glow		
	Power OFF and Green Indicator will not glow		
On pressing the 'main motor ON' Push button	The Bottle-Holding Turret should start indexing in the Clockwise Direction		
Functioning of Heater	The Heater should start the Heating in the machine tank		
Functioning of Pump	After Pressing the Start Button the Pump should start & supply of water to the tank		
	After Pressing the Stop Button the Pump should stop & supply of water stop to the tank		
Functioning of Nozzles	The Nozzles should start wash the Empty Bottles after starting of Pump		
Hot water temperature control	The thermostat should cut off after reaching the set point		
Machine Stop	On pressing the 'Stop' Push Button machine should stop		
Emergency Stop	Machine should stop when Emergency button is pressed		

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
BOTTLE WASHING MACHINE**

PROTOCOL No.:

8.3 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

.....
.....

Reviewed By
Manager QA
Sign/Date:



**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOTTLE WASHING MACHINE**

PROTOCOL No.:

9.0 REFERENCES:

- Installation Qualification
- Operation and Maintenance Manual.

10.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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

12.0 CHANGE CONTROL, IF ANY:

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

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

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

14.0 CONCLUSION:

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



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOTTLE WASHING MACHINE**

PROTOCOL No.:

15.0 RECOMMENDATION:

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

16.0 ABBREVIATIONS:

- No. : Number
- WHO : World Health Organization
- cGMP : Current Good Manufacturing Practices
- QA : Quality Assurance
- DQ : Design Qualification
- IQ : Installation Qualification
- OQ : Operational Qualification
- ID. : Identification
- MMI : Man Machine Interface
- MCB : Miniature Circuit Breaker



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOTTLE WASHING MACHINE**

PROTOCOL No.:

17.0 PROTOCOL POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			