



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
VIAL FILLING & STOPPERING MACHINE**

**PROTOCOL No.:**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
VIAL FILLING & STOPPERING  
MACHINE**

**DATE OF QUALIFICATION**

**SUPERSEDE PROTOCOL No.**

**NIL**



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**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
VIAL FILLING & STOPPERING MACHINE**

**PROTOCOL No.:**

**CONTENTS**

<b>S.No.</b>	<b>TITLE</b>	<b>PAGE No.</b>
<b>1.0</b>	<b>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>Brief Equipment Description</b>	<b>6</b>
<b>6.0</b>	<b>Equipment Specification</b>	<b>7</b>
<b>7.0</b>	<b>Critical Variables to be Met</b>	<b>7</b>
<b>7.1</b>	<b>Process / Product Parameters</b>	<b>7</b>
<b>7.2</b>	<b>Utility Requirement/Location Suitability</b>	<b>7</b>
<b>7.3</b>	<b>Technical Specification/Key Design Features</b>	<b>8</b>
<b>7.4</b>	<b>Material of Construction</b>	<b>10</b>
<b>7.5</b>	<b>Safety</b>	<b>11</b>
<b>7.6</b>	<b>Vendor Selection</b>	<b>12</b>
<b>8.0</b>	<b>Documents to be Attached</b>	<b>12</b>
<b>9.0</b>	<b>Review (Inclusive of Follow Up Action, If Any)</b>	<b>13</b>
<b>10.0</b>	<b>Any Changes Made Against the Formally Agreed Parameters</b>	<b>13</b>
<b>11.0</b>	<b>Recommendation</b>	<b>13</b>
<b>12.0</b>	<b>Abbreviations</b>	<b>14</b>
<b>13.0</b>	<b>Reviewed By</b>	<b>15</b>



**PHARMA DEVILS**

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
VIAL FILLING & STOPPERING MACHINE**

**PROTOCOL No.:**

**1.0 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**

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
VIAL FILLING & STOPPERING MACHINE**

**PROTOCOL No.:**

**2.0 OBJECTIVE:**

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

**3.0 SCOPE:**

- The Scope of this Qualification Document is limited to the Design Qualification of **Vial Filling & Stoppering Machine (Make: Amba Sale & Services) .....**
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.



**PHARMA DEVILS**

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
VIAL FILLING & STOPPERING 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:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review and Approval of the Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.</li><li>• Review of Qualification Protocol cum Report after Execution.</li><li>• Co-ordination with Production and Engineering to carryout Design Qualification.</li><li>• Monitoring of Design Qualification Activity.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of the Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.</li><li>• Review of Qualification Protocol cum Report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of the Protocol cum Report.</li><li>• Assist in the Preparation of the Protocol cum Report.</li><li>• To co-ordinate and support the Activity.</li><li>• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none"><li>➤ GA Drawing.</li><li>➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures.</li><li>➤ Details of utilities.</li><li>➤ Identification of components for calibration.</li><li>➤ Material of construction of all components.</li><li>➤ Brief Process Description.</li><li>➤ Safety Features and Alarms.</li></ul></li><li>• Review of Qualification Protocol after Execution.</li></ul>



**PHARMA DEVILS**

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
VIAL FILLING & STOPPERING MACHINE**

**PROTOCOL No.:**

**5.0 BRIEF EQUIPMENT DESCRIPTION:**

The equipment is an automated means to fill sterile dry powder with different weights in different sizes of vials & rubber Stoppered the same as well pressing of rubber stopper vial. The equipment having four heads with double track filling action. This machine works on vacuum filling principle giving guarantee of high accuracy of fill weight with minimal spillage.

Sterile dry powder loads into powder hopper. Powder hopper will agitate the powder & delivers to the port wheel through powder agitator .When wheel port come under the powder hopper, vacuum will take place.

Powder hopper agitator will push down the powder & due to vacuum in.

Wheel port, powder will enter into the port & fills in it. As soon as wheels start rotating, Doctor Blades will scrap out the excess powder from wheel.

An electro mechanical sensor will sense the presence of vial & pass signal to the solenoid valve. Once powder slug purge into vial, vial separators will carry the vial & pass on the same conveyor belt for the rubber Stoppering process.

Filled vials convey on slat conveyor belt for next operation, as soon as filled vial comes to the lateral belt, same will hold the vial firmly from body diameter & will carry vial underneath the rubber stopper chute, the filled vial will pick one rubber stopper from rubber stopper chute & belt will carry the same vial for pressing the rubber stopper under the two pressing roller.

The first roller will position the rubber stopper & second will press the rubber stopper. Still lateral belts are holding the vial after pressing the rubber stopper, lateral belt will push out the vial on conveyor & conveyor will transfer the vial on scrambler turn table for next Operation.

**6.0 EQUIPMENT SPECIFICATION:**

Equipment Specifications are based on User Requirement Specification prepared for ..... The manufacturer of equipment ensures complies with User Requirement Specification.



PHARMA DEVILS

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
VIAL FILLING & STOPPERING MACHINE**

**PROTOCOL No.:**

**7.0 CRITICAL VARIABLES TO BE MET:**

**7.1 PROCESS/PRODUCT PARAMETERS:**

Critical variables	Acceptance criteria	Reference
<b>Application:</b> Vial Filling & Stoppering Machine is designed to fill sterile dry powder with different weights in different sizes of vials & rubber Stopper the same as well pressing of rubber stopper.	Should be able to filled weight accurately with minimal spillage.	Process Requirement
<b>Working:</b> The machine works on vacuum filling principle.	Filling of material should be highly accurate.	Process Requirement
<b>Electrical Control Panel</b>	The system should have Electrical Control Panel.	Design Requirement

**7.2 UTILITIY REQUIREMENTS/LOCATION SUITABILITY:**

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
<b>Electrical Supply</b>	Voltage : 220 V Phase : 1 Phase Frequency : 50 HZ	GMP Requirement
<b>Room Condition</b>	Temperature : $23 \pm 2$ °C RH : NMT 30 %	Process Requirement
<b>Air supply(Nitrogen gas for dosing)</b>	1 Kg/cm <sup>2</sup>	Process Requirement
<b>Vacuum supply</b>	25 Hg.	Process Requirement



PHARMA DEVILS

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
VIAL FILLING & STOPPERING MACHINE**

**PROTOCOL No.:**

**7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>
<b>Model</b>	AHPF - 250
<b>Dimensions</b>	3168 mm L x 1804mm H x 770 mm W
<b>Main drive assembly</b>	<b>Motor</b> Make : Remi Power : 0.75 kw RPM : 1390 RPM HZ : 50 Hz <b>Gear box</b> Make : Bonfiglioli Power : 0.75 kw RPM : 1390 RPM
<b>Conveyor belt</b>	Quantity : 1 Nos.
<b>Filling head assembly</b>	Quantity : 1 Nos.
<b>Unscrambler &amp; scrambler turn table</b>	<b>Motor</b> Make : Remi Power : 0.25 HP
<b>Powder Hopper</b>	Quantity : 1 Nos.
<b>Port Wheel</b>	Quantity : 1 Nos.
<b>Vial separator assembly or Carriage assembly</b>	Quantity : 1 Nos.
<b>Rubber stopper bowl</b>	Quantity : 1 Nos.
<b>Lateral belt</b>	Quantity : 1 Nos.
<b>Vibrator assembly</b>	Quantity : 1 Nos.
<b>Rubber stopper pressing device assembly</b>	Quantity : 1 Nos.
<b>Vial holding pressing device assembly</b>	Quantity : 1 Nos.
<b>On / Off Main switch</b>	Make : Wago Quantity : 1 Nos. 16 Amp. , 2 Pole





PHARMA DEVILS

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
VIAL FILLING & STOPPERING MACHINE**

**PROTOCOL No.:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>
<b>Indicating Lamp</b>	Make : Technique Quantity : 1 Nos. 220 VAC
<b>Sensor</b>	Make : Accent Quantity : 1 Nos. Inductive Proximity
<b>MCB</b>	Make : Indo Kopp Quantity : 1 Nos. 6 Amp. , 2Pole
<b>Power Relay</b>	Make : PLA Quantity : 1 Nos. 230VAC, 5 Amp
<b>Vibrator Card</b>	Make : Amba Quantity : 1 Nos.
<b>AC Drive Turn Table</b>	Make : Delta Quantity : 1 Nos. 0.5 HP, 220V AC, 1 Phase



PHARMA DEVILS

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
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**PROTOCOL No.:**

**7.4 MATERIAL OF CONSTRUCTION:**

S.No.	Parts Name	Material of construction
1.	Filling Head Assembly	S.S. 304
2.	Unscrambler & Scrambler Turn Table	S.S. 304
3.	Powder Hopper	S.S. 316 L
4.	Port Wheel	S.S. 316 L
5.	Rubber Stopper Bowl	S.S. 316 L
6.	Vibrator Assembly	S.S. 316 L
7.	Conveyor Guide Rail	S.S. 304
8.	Conveyor 'C' Channel	S.S. 304
9.	Universal Joint (for Powder Hopper)	Carbon steel duly clad with S.S
10.	Filling Head & Rubber Stopper Pipe	S.S. 304
11.	Pipe Housing	S.S. 304
12.	Rubber Stopper Pressing Roller	S.S. 304
13.	Vial holding Pressing Device Block	S.S. 304
14.	Vibrator Bowl	S.S. 316 L
15.	Vibrator Bowl Chute	S.S. 316 L
16.	Powder Wheel Piston	S.S. 316 L
17.	Doctor Blade for Hopper	S.S. 316 L



**PHARMA DEVILS**

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
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VIAL FILLING & STOPPERING MACHINE**

**PROTOCOL No.:**

**7.5 SAFETY:**

<b>Critical Variables</b>	<b>Specified Function</b>	<b>Reference</b>
<b>Hardware Emergency switch at Operator Console</b>	For Operator Safety.	Safety Requirement
<b>Vacuum pressure drop interlock</b>	For safety of the batch	Safety Requirement
<b>Motor overload Relay for Vacuum pressure and de dusting blower</b>	For Motor & equipment protection.	Safety Requirement
<b>Air pressure drop interlock</b>	For safety of the batch & the process.	Safety Requirement
<b>Powder low level – Machine stop</b>	For safety of the batch & the process.	Safety Requirement
<b>Rubber stopper low level – Machine stop</b>	For safety of the batch & the process.	Safety Requirement
<b>Motor overload Relay</b>	For Motor & equipment protection.	Safety Requirement



PHARMA DEVILS

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
VIAL FILLING & STOPPERING MACHINE**

**PROTOCOL No.:**

**7.6 VENDOR SELECTION:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Reference</b>
Selection of Vendor for supplying the Vial Filling & Stoppering Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

**Reference:** (1) Specifications and Requirements as specified in PO and URS.

(2) Operating and service manual for Vial Filling & Stoppering Machine.

**8.0 DOCUMENTS TO BE ATTACHED:**

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents.





**PHARMA DEVILS**

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
VIAL FILLING & STOPPERING MACHINE**

**PROTOCOL No.:**

**12.0 ABBREVIATIONS:**

URS	:	User requirement specification
cGMP	:	Current Good Manufacturing Practice
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature circuit breaker
db	:	Decibel
RH	:	Relative Humidity
VFS	:	Vial Filling & Stoppering Machine
SS	:	Stainless Steel



**PHARMA DEVILS**

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**13.0 REVIEWED BY:**

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

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

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<b>HEAD (QUALITY ASSURANCE)</b>			