



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOMATIC TWO HEAD CAPPING MACHINE**

**PROTOCOL No.:**

**DESIGN QUALIFICATION  
PROTOCOL  
CUM REPORT  
FOR  
AUTOMATIC TWO HEAD CAPPING  
MACHINE**

**DATE OF QUALIFICATION**

**SUPERSEDES PROTOCOL No.**

**NIL**



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOMATIC TWO HEAD CAPPING 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>Brief about Equipment</b>                                   | <b>6</b>        |
| <b>6.0</b>   | <b>Equipment Specification</b>                                 | <b>6</b>        |
| <b>7.0</b>   | <b>Critical Variables to be met</b>                            | <b>7</b>        |
| <b>7.1</b>   | <b>Process Parameters</b>                                      | <b>7</b>        |
| <b>7.2</b>   | <b>Utility Requirements / Location Suitability</b>             | <b>7</b>        |
| <b>7.3</b>   | <b>Technical Specifications / Key Design Features</b>          | <b>8</b>        |
| <b>7.4</b>   | <b>Material of Construction</b>                                | <b>9</b>        |
| <b>7.5</b>   | <b>Safety</b>  | <b>10</b>       |
| <b>7.6</b>   | <b>Vendor Selection</b>  | <b>11</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>12</b>       |
| <b>10.0</b>  | <b>Any Changes made against the formally agreed Parameters</b> | <b>12</b>       |
| <b>11.0</b>  | <b>Recommendation</b>  | <b>12</b>       |
| <b>12.0</b>  | <b>Abbreviations</b>   | <b>13</b>       |
| <b>13.0</b>  | <b>Reviewed by</b>   | <b>14</b>       |



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOMATIC TWO HEAD CAPPING MACHINE**

**PROTOCOL No.:**

**1.0 PROTOCOL PRE-APPROVAL:**

**INITIATED BY:**

| DESIGNATION                              | NAME | SIGNATURE | DATE |
|--|------|-----------|------|
| OFFICER/EXECUTIVE<br>(QUALITY ASSURANCE) |      |           |      |

**REVIEWED BY:**

| DESIGNATION           | NAME | SIGNATURE | DATE |
|-----------------------|------|-----------|------|
| HEAD<br>(PRODUCTION)  |      |           |      |
| HEAD<br>(ENGINEERING) |      |           |      |

**APPROVED BY:**

| DESIGNATION                 | NAME | SIGNATURE | DATE |
|-----------------------------|------|-----------|------|
| HEAD<br>(QUALITY ASSURANCE) |      |           |      |



PHARMA DEVILS

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOMATIC TWO HEAD CAPPING MACHINE**

**PROTOCOL No.:**

**2.0 OBJECTIVE:**

- To prepare the Design Qualification document for Automatic Two Head Capping Machine on basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

**3.0 SCOPE:**

- The Scope of this Qualification Document is limited to the Design Qualification for Automatic Two Head capping machine with Sigma-II Model procured.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOMATIC TWO HEAD CAPPING MACHINE**

**PROTOCOL No.:**

**4.0 RESPONSIBILITY:**

The Validation team, 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, Approval and Authorization of the Protocol cum Report.</li> <li>• Assist in the verification of Critical Process Parameters &amp; Drawings as per the Specification.</li> <li>• Post Approval 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 &amp; Drawings as per the Specification.</li> <li>• Post Approval 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 Design Qualification Activity.</li> <li>• To assist in Verification of Critical Process Design Feature &amp; Drawings as per the Specification.</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>• Material of construction of all components</li> <li>• Brief Process Description</li> <li>• Safety Features and Alarms</li> <li>• Post Approval of Qualification Protocol cum report after Execution</li> </ul> |



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOMATIC TWO HEAD CAPPING MACHINE**

**PROTOCOL No.:**

**5.0 BRIEF ABOUT EQUIPMENT:**

The Automatic Two head capping Machine is compact unit totally made of SS structure with height adjustment legs are provided to adjust the machine height and highly efficient machine with elegant look. This multifunctional multi featured machine meets the GMP requirements of labeling for glass and plastic Bottles. The machine requires manual loading and automatic unloading of Bottles.

Two Head capping machine operates in a continuous motion, whereby bottles are fed into the capping area by means of a timing screw, which accelerates and separates the bottles to a pitch which matches the infeed star wheel. Bottles are then transferred through the system from the infeed star wheel via the turret star wheel, onwards to the outfeed star wheel, where they exit the machine. During this process, the caps are simultaneously sorted and fed into the machine along a linear belt into the cap star wheel, where the capping heads descend and picks up the waiting cap and applies it to one of the pre-positioned bottles to a predetermined torque. The whole machine is made of 304 stainless steel and aluminum materials, the standardized design, interchangeable parts, completely according with GMP requirements

**6.0 EQUIPMENT SPECIFICATION:**

Equipment Specification document is provided to manufacturer for engineering equipment & Some critical variables to be met during designing the equipment.



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOMATIC TWO HEAD CAPPING MACHINE**

**PROTOCOL No.:**

**7.0 CRITICAL VARIABLES TO BE MET:**

**7.1 PROCESS PARAMETERS:**

| <b>CRITICAL VARIABLES</b>  | <b>ACCEPTANCE CRITERIA</b>  | <b>REFERENCE</b>            |
|--|---|-----------------------------|
| <b>Application:</b><br><br>Line Speed                            | Conveyor Speed Should be facilitate the easy and efficient as per product requirement i.e. 40-50 CPM                              | Process Requirement         |
| <b>Working:</b><br>Working on Automatic Two Head capping Machine | Automatic Two Head capping Machine should be facilitate the easy & efficient working during the course of the Sealing operations. | Process Requirement         |
| <b>Electrical Control Panel</b>                                  | The system should have Electrical Control Panel.  | Approved Design Requirement |

**7.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY :**

| <b>CRITICAL VARIABLES</b>  | <b>ACCEPTANCE CRITERIA</b>   | <b>REFERENCE</b>            |
|--|--|-----------------------------|
| Utility connections should be available as per the manufacturer's specification. |  |                             |
| Electrical Supply  | The electrical system of the equipment shall be housed as per the cGMP and GEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed in the service area. | Approved Design Requirement |
| Room Condition   | Temperature and RH required as per requirement of product.   | Process Requirement         |



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOMATIC TWO HEAD CAPPING MACHINE**

**PROTOCOL No.:**

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

| S.No. | Parameter          | Specifications  | Reference                   |
|-------|--------------------|---|-----------------------------|
| 1.    | Model              |   | Approved Design Requirement |
| 2.    | Output             | 40-50 CPM   | Process Requirement         |
| 3.    | Conveyor Motor     | Make : Rotomotive<br>0.25 HP/0.18KW/0.5A/230-400V/3<br>Phase/ 50 Hz/1380RPM | Design Requirement          |
| 4.    | Main Device        | Make: Rotomotive<br>1 HP/0.75KW/1.9A/230-400V/3 Phase/<br>50 Hz/ 1380RPM    | Design Requirement          |
| 5.    | Conveyor A.C Drive | Make: Delta<br>0.5 HP, 220-240V,<br>Input: Single Phase<br>Output: 3 Phase  | Design Requirement          |
| 6.    | Main A.C Drive     | Make: Delta<br>1 HP, 220-240V,<br>Input: Single Phase<br>Output: 3 Phase    | Design Requirement          |
| 7.    | Conveyor Gear Box  | Make : Rotomotive<br>Gear Box Ratio : 15:1                                  | Design Requirement          |
| 8.    | Main Gear Box      | Make : Rotomotive<br>Gear Box Ratio : 40:1                                  | Design Requirement          |
| 9.    | Contactor          | Make: C&S   | Design Requirement          |
| 10.   | MCB                | Make: C&S   | Design Requirement          |
| 11.   | Machine Dimension  | 2210mm(L) X 775 mm(W) X 920mm(H)  | Design Requirement          |

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

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

**Inference:**

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

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



**7.4 MATERIAL OF CONSTRUCTION :**

| S.No. | PARTS NAME    | MATERIAL OF CONSTRUCTION |
|-------|---------------|--------------------------|
| 1.    | Machine shell | SS304                    |
| 2.    | Conveyer      | AISI 316                 |
| 3.    | Star wheel    | SS 304                   |
| 4.    | Capping Bowl  | AISI 316                 |
| 5.    | Platform      | SS304                    |
| 6.    | Turret        | AISI 316                 |
| 7.    | Cabinet       | Acrylic                  |

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

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

**Inference:**

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

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



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOMATIC TWO HEAD CAPPING MACHINE**

**PROTOCOL No.:**

**7.5 SAFETY:**

| <b>CRITICAL VARIABLES</b>      | <b>ACCEPTANCE CRITERIA</b>  | <b>REFERENCE</b>   |
|--------------------------------|---|--------------------|
| MCB                            | MCB should be provided so that when there is an overload in current or any short circuit then the MCB trips.  | Safety Requirement |
| Mechanical Guard               | Mechanical guard for all rotating parts should be provided  | Safety Requirement |
| Joints                         | Welding of joints should be Leaving   | Safety Requirement |
| Metal Parts                    | All the metal parts should be properly grounded without any sharp Edges.  | Safety Requirement |
| Leveling And Balancing         | Equipment should be Properly balanced & leveled.  | Safety Requirement |
| Electrical Wiring And Earthing | Electrical wiring should be as per approved drawings. Double external Earthing to control machine (panel and motors) and operator should be provided. | Safety Requirement |
| Noise Level                    | Below 80 db.  | cGMP Requirement   |
| Emergency Switch               | Provided easy access position.  | Safety Requirement |

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

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

**Inference:**

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

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

**7.6 VENDOR SELECTION:**

| CRITICAL VARIABLES  | ACCEPTANCE CRITERIA  | REFERENCE           |
|---|--|---------------------|
| Selection of Vendor for supplying the Automatic Two Head capping machine. | Selection of Vendor is done on the basis of review of vendor.<br><br>Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feed back from market (customers already using the equipment) | Process Requirement |

**Reference:** (1) the equipment shall confirm to the specifications and requirement as specified in PO and URS  
 (2) Operating and service manual for Automatic two Head capping Machine.

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

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

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

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



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOMATIC TWO HEAD CAPPING MACHINE**

**PROTOCOL No.:**

**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

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

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

**10.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:**

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

**11.0 RECOMMENDATION:**

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



PHARMA DEVILS

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOMATIC TWO HEAD CAPPING MACHINE**

**PROTOCOL No.:**

**12.0 ABBREVIATION:**

|        |   |                                     |
|--------|---|-------------------------------------|
| URS    | : | User Requirement specification      |
| DQ     | : | Design Qualification                |
| cGMP   | : | Current Good Manufacturing Practice |
| cGEP   | : | Current Good Engineering Practice   |
| Ltd.   | : | Limited                             |
| QA     | : | Quality Assurance                   |
| PO     | : | Purchase Order                      |
| Kg     | : | Kilogram                            |
| mm     | : | Millimeter                          |
| SS     | : | Stainless Steel                     |
| MOC    | : | Material of Construction            |
| P & ID | : | Piping and Instrumentation Diagram  |
| Db     | : | Decibel                             |



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOMATIC TWO HEAD CAPPING MACHINE**

**PROTOCOL No.:**

**13.0 REVIEWED BY:**

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

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

**APPROVED BY:**

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