



**PHARMA DEVILS**

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
SEMI AUTOMATIC CRIMPING MACHINE**

**PROTOCOL No.:**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
CRIMPING MACHINE**

**DATE OF QUALIFICATION**

**SUPERSEDE PROTOCOL No.**

**NIL**



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**1.0 PRE – APPROVAL:**

**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER /EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

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

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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**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 Semi Automatic Crimping Machine (Make: **Speed Line Aerosol.**) for Ointment Section.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.



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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 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,</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>➤ 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></ul></li><li>• Review of Qualification Protocol after Execution.</li></ul>



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**5.0 BRIEF EQUIPMENT DESCRIPTION:**

A Hollow S.S. cylindrical assembly consisting a piston inside, Assembled with crimping tool, which is operated by approximately 6.0 kg/cm<sup>2</sup> air pressure. Height of crimping assembly shall be adjusted by knob & hand wheel mounted on top of the cylinder. Air pressure shall be controlled by pressure gauge which is assembled on lower side of the mounting S.S. table. A Press peddle also available for operation of crimping machine.

**6.0 EQUIPMENT SPECIFICATION:**

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

**7.0 CRITICAL VARIABLES TO BE MET:**

**7.1 PROCESS/PRODUCT PARAMETERS:**

PARAMETERS	SPECIFICATION	REFERENCE
Pneumatically operated	Single cylinder crimping machine	Process Requirement
MOC	SS304	Process Requirement
Pneumatically cylinder Bore diameter 127 mm x Stroke 70 mm	Bore diameter 127 mm x Stroke 70 mm	Design Requirement
Collet	36 teeth	Design Requirement
MOC	Spring Steel	
Mounted on table size	1000 mm x 750 mm x 900 mm Height	Design Requirement
Machine Adjustments	Crimp Diameter, Crimp Depth, Can Height, Can Diameter.	Design Requirement

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

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



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**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.		
<b>Compressed air pressure supply</b>	6 bar continuous	Process Requirement

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

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



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**7.3 TECHNICAL SPECIFICATION / KEY DESIGN FEATURE:**

PROCESS REQUIREMENT	PROCESS REQUIREMENT	PROCESS REQUIREMENT
Equipment name	Semi-Automatic Crimping machine	Design Requirement
Make	Speed Line Aerosol	Design Requirement
Pneumatically operated	Single cylinder crimping machine	Process Requirement
MOC	SS304	Process Requirement
Pneumatically cylinder Bore diameter 127mm X Stroke 70 mm	Bore diameter 127mm X Stroke 70 mm	Design Requirement
Collet	36 teeth	Design Requirement
MOC	Spring Steel	
Mounted on table size	1000 mm x 750 mm x 900 mm Height	Design Requirement
Pneumatics	FESTO/MERCURY	Design Requirement
Controls	Pneumatic Push button / Pneumatic foot pedal.	Design Requirement
Machine Adjustments	Crimp Diameter, Crimp Depth, Can Height, Can Diameter.	Design Requirement

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

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





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**8.0 DOCUMENTS TO BE ATTACHED:**

- Any other relevant documents.

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

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

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**11.0 RECOMMENDATION:**

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**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
db	:	Decibel
RH	:	Relative Humidity
SS	:	Stainless Steel
QA	:	Quality Assurance



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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>OPERATING MANAGER (QUALITY ASSURANCE)</b>			

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

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