



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE VISUAL INSPECTION  
CONVEYOR**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
ONLINE VISUAL INSPECTION  
CONVEYER**

<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



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CONVEYOR**

**PRTOCOL 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 Equipment Description</b>	<b>6-7</b>
<b>6.0</b>	<b>Equipment Specification</b>	<b>7</b>
<b>7.0</b>	<b>Critical Variables to be Met</b>	<b>8</b>
<b>7.1</b>	<b>Process/Product Parameters</b>	<b>8</b>
<b>7.2</b>	<b>Utility Requirement/Location Suitability</b>	<b>8</b>
<b>7.3</b>	<b>Technical Specification/Key Design Features</b>	<b>9</b>
<b>7.4</b>	<b>Material of Construction</b>	<b>10</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>Document to be Attached</b>	<b>11</b>
<b>9.0</b>	<b>Review (Inclusive of Follow Up Action, If Any)</b>	<b>11</b>
<b>10.0</b>	<b>Any Change Made Against the Formally Agreed Parameter</b>	<b>11</b>
<b>11.0</b>	<b>Recommendation</b>	<b>12</b>
<b>12.0</b>	<b>Abbreviations</b>	<b>12</b>
<b>13.0</b>	<b>Reviewed by</b>	<b>13</b>



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE VISUAL INSPECTION  
CONVEYOR**

**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)			



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE VISUAL INSPECTION  
CONVEYOR**

**2.0 OBJECTIVE:**

- To prepare the Design Qualification document for Online Visual Inspection Conveyor 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 of **Online Visual Inspection Conveyor (Make: .....)**.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE VISUAL INSPECTION  
CONVEYOR**

**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
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Authorization 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>• 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></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>



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE VISUAL INSPECTION CONVEYOR**

**5.0 BRIEF EQUIPMENT DESCRIPTION:**

The purpose of the **Online Visual Inspection Conveyor 15 Feet (Model: .....)** is to convey & inspect the specific size and shape of IV Bottle at the variable speed according to requirement of feeding to the next unit.

Complete machine can be divided in following sub sections.

**MAIN ASSEMBLY:**

1. Structure of Machine
2. Mechanism of drive unit with selector switch operating panel
3. Conveyor belt and platform
4. Inspection booth with both side black & white radium film

**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:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>Application:</b> The Online Visual Inspection Conveyor shall be able to convey the inspected bottle	The Online Visual Inspection Conveyor should be able for convey the inspected bottle.	Process Requirement
<b>Working:</b> Working of Online Visual Inspection Conveyor	Online Visual Inspection Conveyor should capable to Deliver with desired uniformity as per product requirement.	Process Requirement
<b>Electrical Control Panel</b>	The system should have Electrical Control Panel.	Design Requirement



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE VISUAL INSPECTION  
CONVEYOR**

**7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>Electrical Supply</b>	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards, with adequate safety.	cGMP Requirement
<b>Room Condition</b>	Temperature and RH requirement as per requirement of product	Process Requirement

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

<b>NAME OF THE COMPONENT</b>	<b>TECHNICAL SPECIFICATION</b>	<b>REFERENCE</b>
Material of construction	SS-304, MATT FINISH	Design Requirement
External size	4575 mm (L) x 925 mm (W) x 1566 ± 50 mm (H)	Design Requirement
Working size	850 ± 50mm	Design Requirement
Weight	150 kg Approx.	Design Requirement
Power supply	1 Phase, 230 V, 50 Hz	Design Requirement
Electric Motor : 01 Nos.	Make : Rotomotive Type : 3 Phase Squirrel cage induction motor (71B - 4 ) RPM : 1350 KW/HP : 0.37 / 0.5 Sr. No. :M05171021	Design Requirement
Gear Box – 01 Nos.	Make : Rotomotive PAM : 71B5 I : 20:1 M. Type : BOX 040 Sr. No : G05170968	Design Requirement
Variable Frequency Drive – 01 Nos.	Make : Delta Model : VFD004L21A KW/HP : 0.4/ 0.5 I/P Supply : 1 Phase,6.5A/3PH 2.7A 200-240V, 50-60 HZ O/P Supply : 3Phase, 0 - 240 V, 2.5A, 0.4KVA	Design Requirement



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE VISUAL INSPECTION  
CONVEYOR**

NAME OF THE COMPONENT	TECHNICAL SPECIFICATION	REFERENCE
	Sr. No. 004L21A6W17111190	
Pot – 01 Nos.	Make : Pankaj Model : RW-3 Range : 10 K $\Omega$	Design Requirement
ON/OFF Switch – 01 Nos.	Make : Salzer Type : 3 Pole, 6 – Amp., 440V AC	Design Requirement
Conveyor Belt – 01 Nos.	Size : 9040 X 455 X 2.1mm MOC : Rubberized Endless PVC Belt	Design Requirement
Legs Pad – 06 Nos.	Size: 78 mm Dia. MOC : SS 304 & UHMW Ring	Design Requirement
Legs Bolt – 06 Nos.	Size: 180mm Length. MOC : SS304	Design Requirement
Tube Light- 08Nos.	Make : Local Rating : 40W, 0.4 Amp I/P Supply : 1 Phase, 230 V AC, 50HZ	Design Requirement

**7.4 MATERIAL OF CONSTRUCTION:**

MACHINE PARTS	ACCEPTANCE CRITERIA
Conveyor Belt	Endless Rubberized Belt
Drive Shaft	MS
Platform	SS 304
All Nuts and Bolts	SS 304
Panel Box	SS 304
Inspection Booth	SS 304 with Black & White Radium Film
Legs Bolt & Pad	SS 304 with UHMW Ring





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**7.5 SAFETY:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>MCB</b>	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips	Safety Requirement
<b>Mechanical Guard</b>	Mechanical guard for all rotating parts.	Safety Requirement
<b>Joints</b>	Welding of joints without any welding burrs	Safety Requirement
<b>Metal Parts</b>	All the metal parts should be Properly grind without any sharp edges.	Safety Requirement
<b>Leveling And Balancing</b>	Equipment should be properly balanced & leveled	Safety Requirement
<b>Electrical Wiring And Earthing Device</b>	Electrical wiring should be as per approved drawings. Earthing device to protect to operator from electric shock.	Safety Requirement
<b>Noise Level</b>	Below 80 db	GMP & Safety Requirement
<b>Emergency Switch</b>	Provided easy access position	GMP & Safety Requirement

**7.6 VENDOR SELECTION:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>Selection of Vendor for supplying the Online Visual Inspection Conveyor</b>	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

**Reference:** (1) User Requirement Specifications (URS).

(2) Design & Functional Specifications provided by Vendor.

**8.0 DOCUMENTS TO BE ATTACHED:**

- GA Drawing or Approved Design and Specifications.
- Any other relevant documents.



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CONVEYOR**

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

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

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**11.0 RECOMMENDATION:**

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**12.0 ABBREVIATIONS:**

- AISI : American Iron Steel Institute
- cGMP : Current Good Manufacturing Practice
- DQ : Design Qualification
- GA : General Arrangement
- mm : Millimeter
- MOC : Material of Construction
- QA : Quality Assurance
- SS : Stainless Steel
- STD : Standard
- URS : User requirement specification.
- VIC : Online Visual Inspection Conveyer



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CONVEYOR**

**13.0 REVIEWED BY:**

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

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

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