DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VIAL OPTICAL INSPECTION MACHINE

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VIAL OPTICAL INSPECTION MACHINE	PROTOCOL No.:

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PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VIAL OPTICAL INSPECTION MACHINE	PROTOCOL No.:

1.0 PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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 for **Vial Optical Inspection Machine (Make: Ambica Pharma Machines Private Limited)** to be installed in Packing Hall.
- The equipment shall operate under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by vendor shall be verified during Design Qualification.

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	• Initiation, Review and Approval of the Qualification Protocol cum Report • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution.
Engineering	• Review of the Qualification Protocol cum Report • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. ➢ GA Drawing. ➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/brochures. ➢ Details of utilities Required. ➢ Identification of components for calibration. ➢ Material of construction of Product Contact Parts. ➢ Brief Process Description. ➢ Safety Features. • Review of Qualification Protocol cum Report after Execution.

5.0 BRIEF PROCESS DESCRIPTION:

In Vial Optical Inspection Machine, an operator can check / inspect whether the vial contains any foreign particles, broken vial or not properly sealed vial, with the help of speed adjustment provision, spin rotation of vial, mirror & magnifying glass. The working of this machine is very simple. Normally this process is done once the vial is filled and sealed.

From the Unscrambler with the help of the guides the vials move to the Nylon Chain Roller. These rollers are responsible for the movement of the vials. On the backside of the conveyor glass mirrors are fixed so that the operators can visually check the vial without hand touch. This machine is suitable for four operators, two operators on each side. Each operator has been provided with his or her inspection section. It means that each operator has separate inspection area in which they have to do the inspection. The inspection area is illuminated with the help of tube light, which is fitted on the top of the inspection hood on the inner side.

The rollers move round which in turns the vial round so that the operator can see from every side. The operator has to see the same on the mirror which is fitted on the back side of the conveyor. Then it moves towards. During the inspection, if the operator finds that one of the vial is not properly sealed or some particles are mixed up with the powder then the same is to be picked up from the roller and drop it to the rejection box. After the inspection is over it moves for the vial labeling section.

Vial Optical Inspection Machine is equipped with SS square frame Turn Table and is useful to ensure total synchronization, uniform flow of vial. Vial inputs in turn table by manually or automatic will rotate on disk of turn table and exit through a SS strip, will guide the container towards outlet path.

6.0 EQUIPMENT SPECIFICATION:

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

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
• Speed of Roller Conveyor. • Spin Rotation of Vial. • Mirror. • Magnifying Glass.	• Speed can be adjusted 01 to 50 RPM with the help of Variable Frequency Drive. • Nylon chain roller provides the spin rotation of vials in anti-clockwise direction towards the scrambler side so that the operator can see the rotating vials from every side with the help of mirror and magnifying glass. • On the backside of the conveyor viewing mirrors are fixed to visually check the vials without hand touch. • Magnifying glasses can be adjusted as per suitability of operator.	Process Requirement

7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
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 cGEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed in service area.	GMP Requirement
Room Condition	Temperature and RH required as per requirement of product.	Process Requirement

7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S. No.	Critical Variables	Acceptance Criteria
1.	**Equipment**	Vial Optical Inspection Machine
2.	**Model**	AVIN - 240
3.	**Output**	0-240 Vials per Minute
4.	**Dimension**	3360 (L) mm X 1100 (W) mm X 835 ± 50 (H) mm
5.	**Conveyer Height**	As per Line Height
6.	**Net Weight**	450 Kg
7.	**Gross Weight**	600 Kg
8.	**Main Motor & Gear box**	Nos. : 02 (01 No. Left & 01 No. Right)
9.	**Motor & Gear Box for Conveyer**	**Motor & Gear Box for Conveyer (Left)** Make : Bonfiglioli Riduttori S. No. : 71596220310 Electric Supply : 50 Hz, 380- 415 V, 0.72-0.74 A Electric Supply : 60 Hz, 440- 480 V, 0.68-0.71 A **Motor & Gear Box for Conveyer (Right)** Make : Bonfiglioli Riduttori S. No. : 71596220318 Electric Supply : 50 Hz, 380- 415 V, 0.72-0.74 A Electric Supply : 60 Hz, 440- 480 V, 0.68-0.71 A **Motor & Gear Box for Turn Table** Nos. : 02 Make : Bonfiglioli

S. No.	Critical Variables	Acceptance Criteria
10.	**Turn Table**	Make : Ambica Pharma Machines Private Limited Nos. : 02 Direction of Rotation: Clockwise/ Anti clockwise (As per requirement). Electric Supply: 50 Hz, 03 Phase, 415 V, 0.5 HP.
11.	**VFD**	Nos. : 04 (02 Nos. Left & 02 Nos. Right) (Left 1st for Conveyer & Left 2nd for Turn Table). (Right 1st for Turn Table & Right 2nd for Conveyer). Speed : 01-50 RPM
12.	**Digital Display for VFD**	Make : Delta Nos. : 04 (Left 1st for Conveyer & Left 2nd for Turn Table). (Right 1st for Turn Table & Right 2nd for Conveyer). Electric Supply : 50 Hz, 01 Phase, 230 V, 0.4 kW
13.	**Tube light Frame**	Make : Havells Nos. : 04 (02 Nos. Left & 02 Nos. Right)
14.	**Magnifying Glass**	Nos. : 04 (02 Nos. Left & 02 Nos. Right)
15.	**Mirror**	Nos. : 04 (02 Nos. Left & 02 Nos. Right)
16.	**Conveyer ON/OFF Switch**	On Switch (Green) Nos. : 02 (01 No. Left & 01 No. Right) OFF Switch (Red) Nos. : 02 (01 No. Left & 01 No. Right)
17.	**Turn Table ON/OFF Switch**	Nos. : 02 (01 No. Left & 01 No. Right)
18.	**Main Electrical Supply Switch (Tube Light ON/OFF Switch)**	Nos. : 02 (01 No. Left & 01 No. Right)
19.	**Chain Sprockets**	Make : Mild Steel duly Zinc Plated.

S. No.	Critical Variables	Acceptance Criteria
20.	**Chain**	Make : Rolon

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of Construction	Reference
1.	**Rollers**	Nylon	Process Requirement
2.	**Roller Pin**	SS 316	GMP Requirement
3.	**Doors & Covers**	SS 316	GMP Requirement
4.	**Chain Covers**	SS 304	GMP Requirement
5.	**Main Hood**	SS 304	GMP Requirement
6.	**Conveyer Plates**	SS 304	GMP Requirement
7.	**Conveyer Shafts**	SS 304	GMP Requirement
8.	**Conveyer Collars**	SS 304	GMP Requirement
9.	**Machine Frame**	SS 304 Square pipe frame Structure	Process Requirement
10.	**Inverter Channels**	Delrin	Process Requirement
11.	**Turn Table Plate**	Aluminium Casting duly cladded by SS Sheet	Process Requirement
12.	**All Gide Plates**	SS 304	GMP Requirement
13.	**Shafts**	M.S. Zinc Plated	GMP Requirement
14.	**Covers**	SS 304	GMP Requirement
15.	**Magnifying Glass**	Fiber	Process Requirement
16.	**Turn Table**	SS 304	GMP Requirement

7.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
MCB	MCB is 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.	Safety Requirement
Joints	Welding of joints without any welding burrs.	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	Safety Requirement

7.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Vial Optical Inspection Machine	Selection of Vendor is done on the basis of review of vendor. Criteria for review were 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) The equipment shall confirm to the specifications and requirement.

(2) Operating and service manual for Vial Optical Inspection Machine.

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 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
cGEP	:	Current Good Engineering Practice
PO	:	Purchase Order
DQ	:	Design Qualification
Kg	:	Kilogram
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature Circuit Breaker
db	:	Decibel
RH	:	Relative Humidity
RPM	:	Revolution per Minute
HP	:	Horse Power
AMP	:	Ampere
STD	:	Standard
kW	:	Kilo Watt
V	:	Volt
Hz	:	Hertz
NLT	:	Not Less Than
VOI	:	Vial Optical Inspection Machine

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			