



PHARMA DEVILS

**DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
CHECK WEIGHER MACHINE**

PROTOCOL No.:

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
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DATE OF QUALIFICATION

SUPERSEDES PROTOCOL CUM REPORT No.

NIL



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1.0 PROTOCOL 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)			



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2.0 OBJECTIVE:

- To prepare the Design Qualification of Check Weigher Machine on the basis of User Requirement Specification, Purchase Order and information given by Supplier.
- To ensure that all Critical Equipment / 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 check weigher Machine procured from (**Make :**).
- The equipment shall operate under the controlled 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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Review and Approval of Design Qualification Protocol cum Report.• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification activity.• Review of Design Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review of Design Qualification Protocol cum Report.• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.• Review of Design Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review of Design 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• Identification of components for calibration• Material of construction of all components• Brief Equipment Description• Safety Features and Alarms• Review of Design Qualification Protocol cum Report after Execution.



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5.0 BRIEF PROCESS DESCRIPTION:

- Check weigher Machine is intended to be used for online weight checking of vials.
- Check weighing after the filling and capping before labeling of vials.
- To check the empty vials and missing dropper from the vials.
- The product images can be uploaded from USB memory.

6.0 EQUIPMENT SPECIFICATION:

- Equipment Specification is a document provided by manufacturer for engineering equipment as per the specifications.



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7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Inlet, Weighing & Exit Conveyor	Width: 220mm Length: 350mm	Design Requirement
Material of construction for all product contact part	Food Grade Material Conveyor Belt	Design Requirement
Material of construction for all product non-contact part	Stainless Steel – Grade 304 ABS Resin	Design Requirement
Conveyor Belt mounting	Direct Gear Drive from motor to belt	Design Requirement
Rejection Mechanism	Conveyor Drop	Design Requirement
Actuator	SMC make 24VDC Solenoid	Design Requirement
Load Cell	Digital Load cell for weighing conveyor	Design Requirement
Motor	DC Motor EC Flat 45 Auto Speed setting no VFD	Design Requirement
Photo Sensor	Placed between infeed and weighing conveyor for counting the no. of product passed	Design Requirement

7.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Electricity Supply with proper Earthing	Voltage: Single phase AC100V – 240 V (+10% / -15%), Frequency: 50/60Hz 180VA	Design Requirement



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7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

7.3.1 TECHNICAL SPECIFICATION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Model	AD-4961-2KD-2035	Design Requirement
Capacity	500 gm / 2,000 gm	Design Requirement
Sr.No.	Design Requirement
Resolution	0.01 gm / 0.1 gm	Design Requirement
Accuracy (3 σ)*1	0.08 gm / 0.18 gm	Design Requirement
Max. throughput	320pcs/min.	Design Requirement
Conveyor belt width	200 mm	Design Requirement
Conveyor length	350 mm	Design Requirement
Transport medium	Urethane belt	Design Requirement
Conveyor belt speed	15 – 120m/ min.	Design Requirement
Max. product dimensions	Length: 30 – 300 mm Width: 200 mm	Design Requirement
Weighing sensor	Strain gauge load cell	Design Requirement
Display	7inch touch panel color display (WVGA)	Design Requirement
Operation method	Touch panel (resistive film type), operation buttons	Design Requirement
Number of recorded items	1,000 items (10 groups x 100 items)	Design Requirement
Communication functions	Modbus TCP / Modbus RTU/ RS-232C/485 (selectable) / TCP/IP(PostScript printer)/USB (for PostScript printer, USB memory, data storage, image import use)*3	Design Requirement
External input	Non-Voltage contact input 4points	Design Requirement
External output	Relay output 8points	Design Requirement
Dust / Water resistance specifications	IP65	Design Requirement
Operation temperature / humidity range	5 - 40 ⁰ C / humidity below 85% (with no condensation)	Design Requirement
Power supply * 4	Single phase AC100V – 240 V (+10% / -15%), 50/60Hz 180VA	Design Requirement
External dimensions * 2	Length: 700mm / Width: 660mm / Height: 710 – 860mm	Design Requirement
Weight * 2	Approx. 35 Kg.	Design Requirement
Material	Display: ABS resin	Design Requirement
	Conveyor unit: Aluminum (alumite coating) and PP resin	Design Requirement
	Control box: Stainless steel	Design Requirement
	Base unit: Stainless steel	Design Requirement



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7.3.2 DESCRIPTION OF INDIVIDUAL MACHINE PARTS :

DESCRIPTION	CRITERIA	REFERENCE
Surface Finish	Mirror and mat finish	Design Requirement
Conveyor	Food grade and HACCP complaint conveyor belt	Design Requirement
Control Box and Base unit	Stainless Steel – Grade 304	Design Requirement
Top Cover	Breeze break for weighing stability and cover for running conveyors	Design Requirement
Rejecter	Over & underweight variation Other machine signal rejection Foreign product rejection	Design Requirement
In put & out put	8 Digital output 4 Digital input	Design Requirement
Platform		
No Sharp edges	Rounded Edges	Design Requirement
Conveyor	No timing belt	Design Requirement
Motor	No open motor	Design Requirement
External Contamination	Stainless Steel 304 construction Round edge legs and body	Design Requirement
Control Box	Lockable box and no open wires for safety	Design Requirement

7.4 MATERIAL OF CONSTRUCTION:

Sr. No.	COMPONENTS	MOC	REFERENCE
1.	Control Box and Base unit	Stainless Steel, grade 304	Design Requirement
2.	Display unit	ABS Resin	Design Requirement
3.	Conveyor Belt	Urethane Material Belt	Design Requirement
4.	Conveyor Unit	Aluminium (alumite coating) and PP Resin	Design Requirement



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7.5 SAFETY FEATURE :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
No Sharp Edges	Rounded Corners	Safety Requirement
Motor	No open motor and no timing belt for safety and reduce accident of risk	Safety Requirement
Electrical & Electronic Guard	Safely enclosed control box and display unit. Proper wire earthing	Safety Requirement
External Components	All external material used are of stainless steel 304 and Food grade	Safety Requirement

7.5 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for check weigher Machine is reject the over & underweight variation other machine signal rejection foreign product rejection.	Selection of Vendor is done on the basis of review of vendor. Criteria for review include Vendor Background (General / Financial), Technical Know How, Quality Standards, Inspection of Site, Costing, and Feed Back from Market etc.).	cGMP Requirement

Reference: (1) The equipment shall confirm to the specifications and requirement as specified in PO.
(2) Operating and service manual for Check weigher Machine shall be provided at the time of delivery of the equipment.

Checked By
Engineering
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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8.0 DOCUMENTS TO BE ATTACHED:

- Instruction Manual
- Assembly Guide
- Certificate of MOC
- Dimension Drawing
- Purchase Order Copy

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:

AC	:	Alternative Current
cGMP	:	Current Good Manufacturing Practice
CWM	:	Check Weigher Machine
DC	:	Direct Current
DQ	:	Design Qualification
Gm	:	Gram
Hz	:	Hertz
mm	:	Millimeter
MOC	:	Material of Construction
No.	:	Number
PO	:	Purchase Order
QA	:	Quality Assurance
SS	:	Stainless Steel
URS	:	User Requirement Specification
V	:	Volt



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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			