



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
CHECKWEIGHER MACHINE**

**PROTOCOL CUM  
REPORT No.:**

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

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Packing Hall</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES No.</b>	<b>NIL</b>



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**1.0 PROTOCOL PRE – APPROVAL:**

**PREPARED BY:**

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

**REVIEWED BY:**

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

**APPROVED BY:**

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



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**2.0 OBJECTIVE:**

- To provide documented evidence for the Installation Qualification of Checkweigher Machine.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

**3.0 SCOPE:**

The scope of this installation qualification protocol cum report is limited to qualification of Check Weigher Machine to be installed in Packing Hall.

- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Check Weigher Machine.



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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, Authorization and Compilation of the Installation Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Installation Qualification.</li><li>• Monitoring of Installation Qualification Activity.</li><li>• Post Authorization of Installation Qualification Protocol cum Report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Installation Qualification Protocol cum Report.</li><li>• To Co-ordinate and support for Execution of Qualification study as per Protocol.</li><li>• Post Approval of Installation Qualification Protocol cum Report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of Installation Qualification Protocol cum Report.</li><li>• Co-ordination, Execution and technical support in Check Weigher Machine Installation Qualification Activity.</li><li>• Calibration of Process Instruments.</li><li>• Responsible for Trouble Shooting (if occurs during execution).</li></ul>



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**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Check Weigher Machine
<b>Equipment</b>	-
<b>Manufacturer's Name</b>	-
<b>Supplier Name</b>	-
<b>Machine Serial No.</b>	-
<b>Model</b>	-
<b>Location of Installation</b>	Packing Hall

**6.0 SYSTEM DESCRIPTION:**

The Checkweigher Machine contains display conveyor belt control box automatic sensor for over & underweight variation other machine signal rejection foreign product rejection

The Checkweigher Machine consists of following Parts:-

- Infeed conveyor
- Photo sensor/reflector
- Weighing conveyor
- Display
- Control box
- Power switch
- Rejecter (option)
- Rejecter conveyor (option)



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**7.0 PRE – QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**

- Executed and approved design qualification document
- Electrical circuits diagram
- Technical specification of equipment
- Certificate of material of construction of components.

**7.1.1 Procedure:**

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

**7.1.2 Acceptance Criteria:**

- All the documents should be available, complete and approved by respective authorities.



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**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 General Checks and Location Suitability:**

<b>INSTALLATION CHECKS</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	Packing Hall		
Room Condition	General working condition		
Illumination in area	NLT 300 Lux.		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

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

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

**Inference:**

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





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**8.2 EQUIPMENT VERIFICATION:**

**8.2.1 TECHNICAL SPECIFICATIONS:**

<b>PARAMETERS</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION Complies/ Non Complies</b>	<b>OBSERVED BY (ENGINEERING) (SIGN/DATE)</b>
Model	-		
S. No.	-		
Capacity	500 gm / 2,000 gm		
Resolution	0.01 gm / 0.1 gm		
Accuracy (3 $\sigma$ )*1	0.08 gm / 0.18 gm		
Max. throughput	150 pcs. / min.		
Conveyor belt width	200 mm		
Conveyor length	350 mm		
Transport medium	Urethane belt		
Conveyor belt speed	15 – 120 m/min.		
Max. product dimensions	Length: 30 – 300 mm Width: 200 mm		
Weighing sensor	Strain gauge load cell		
Display	7inch touch panel color display (WVGA)		
Operation method	Touch panel (resistive film type), operation buttons		
Number of recorded items	1,000 items (10 groups x 100 items)		
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		
External input	Non-Voltage contact input 4 points		
External output	Relay output 8 points		
Dust / Water resistance specifications	IP 65		
Operation temperature	5 - 40 <sup>0</sup> C / humidity below		



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<b>PARAMETERS</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION Complies/ Non Complies</b>	<b>OBSERVED BY (ENGINEERING) (SIGN/DATE)</b>
/ humidity range	85% (with no condensation)		
Power supply * 4	Single phase AC100V – 240 V (+10% / -15%), 50/60Hz 180VA		
External dimensions * 2	Length: 700 mm / Width: 660 mm / Height: 710 – 860 mm		
Weight * 2	Approx. 35 Kg.		
Material	Display: ABS resin		
	Conveyor unit: Aluminum (alumite coating) and PP resin		
	Control box: Stainless steel		
	Base unit: Stainless steel		

**Checked By  
Production**

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

**Verified By**

**Quality Assurance**

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

**Inference:**

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**Reviewed By  
Manager QA**

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



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**8.2.2 INSTALLATION CHECKS:**

Specification	OBSERVATION Complies/ Non Complies	Observed by (Engineering) (Sign/Date)
The delivered Checkweigher Machine, options and accessories match the order description.		
Options and accessories are properly connected to Checkweigher Machine.		
No external damage affects the accuracy.		
Installation environment	Temperature range (5.0 to 40.0 <sup>o</sup> C)	
	Humidity (Below 85.0%)	
	No condensation	
Use a solid table or base for the Checkweigher Machine and avoid vibration.		
Ensure that the instrument is level by adjusting the adjuster bolt.		
Avoid installing the Checkweigher Machine near air conditioners or in an area exposed to direct sunlight.		
Install the instrument away from magnetically charged substances.		
Install the instrument away from areas where dust accumulates.		
Cables should be routed so that they cannot be damaged or hinder daily operations.		
Maximum capacity 500 / 2,000 gm		
Minimum resolution 0.01 gm / 0.1 gm		
Main power turns on without problems		

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

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

**Inference:**

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



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**8.3 MOC Verification List:**

<b>S.No.</b>	<b>COMPONENTS</b>	<b>MOC</b>	<b>OBSERVATION Complies/ Non Complies</b>	<b>OBSERVED BY (ENGINEERING) (SIGN/DATE)</b>
1.	Control Box and Base unit	Stainless Steel, grade 304		
2.	Display unit	ABS Resin		
3.	Conveyor Belt	Urethane Material Belt		
4.	Conveyor Unit	Aluminium (alumite coating) and PP Resin		

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

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

**Inference:**

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



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**8.4 Safety:**

<b>CHECKS</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION Complies/ Non Complies</b>	<b>OBSERVED BY ENGINEERING (SIGN/DATE)</b>
No Sharp Edges	Rounded Corners		
Motor	No open motor and no timing belt for safety and reduce accident of risk		
Electrical & Electronic Guard	Safely enclosed control box and display unit. Proper wire earthing		
External Components	All external material used are of stainless steel 304 and Food grade		

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

**Verified By**  
**Quality Assurance**  
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**Inference:**

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



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**8.5 UTILITIES PROVIDED:**

<b>PARAMETERS</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION COMPLIES/ NON COMPLIES</b>	<b>OBSERVED By (ENGINEERING) (SIGN/DATE)</b>
Electricity	Voltage: AC100V-240V (+10% / - 15%), 50-60 Hz 180VA		
Light Indication for machine / instrument working Condition	Shall be properly connected and identified		

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

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

**Inference:**

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



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**9.0 REFERENCES:**

- Validation Master Plan
- Design Qualification Protocol Cum Report
- Instruction Manual
- P & ID
- Electrical Diagram

**10.0 DOCUMENTS TO BE ATTACHED:**

- Instruction Manual
- Assembly Guide
- Dimension Drawing

**11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:**

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**12.0 CHANGE CONTROL, IF ANY:**

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

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**14.0 CONCLUSION:**

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**15.0 RECOMMENDATION:**

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**16.0 ABBREVIATIONS:**

cGMP	:	Current Good Manufacturing Practices
CWM	:	Check Weigher Machine
DQ	:	Design Qualification
QB	:	Quality block
IQ	:	Installation Qualification
mm	:	Millimetre
MOC	:	Material of Construction
QA	:	Quality Assurance
RH	:	Relative Humidity
Sr.	:	Serial No.
WHO	:	World Health Organization



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**17.0 PROTOCOL POST -APPROVAL:**

**PREPARED BY:**

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

**REVIEWED BY:**

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

**APPROVED BY:**

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