OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACKING MACHINE

EQUIPMENT ID No.	
LOCATION	**Packing**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STRIP PACKING MACHINE	PROTOCOL No.:

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 PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STRIP PACKING 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 verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Strip Packing Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of **Strip Packing Machine** (**Make- Sharma Engineering Works**) to be installed in the Packing.
- This Protocol will define the methods and documentation used to perform OQ activity the Strip Packing Machine for OQ. Successful completion of this Protocol will verify that Strip Packing Machine meet all acceptance criteria and ready for Performance 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	• Preparation, Approval and compilation of the operational Qualification protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process.
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol after Execution
Engineering	• Review of Operational Qualification. • To co-ordinate and support Operational Qualification Activity. • Calibration of Process Instruments.

5.0 EQUIPMENT DETAILS:

Equipment Name	Strip Packing Machine
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Model	GMP model
Location of Installation	Packing

6.0 EQUIPEMENT DESCRIPTION:

Feeding System:

Product is fed into the hopper from where it is guided into the Bowl mounted on a Vibrator. The product on the Bowl is evenly distributed and guided through the tracks on the Bowl into the Chute Channel and the feed rate of the Product from the Bowl to the Chute Channel is controlled by the Vibrator. The Product from the Chute is released onto the Sealing Roller by the Cam Operated Release Pin.

Sealing System:

The set of Sealing Rollers draws the heat sealing Packing Material (Foils) from 2 sets of front adjustable type of friction brake system Foil Holder Assembly and Foil running tubes. The sealing Rollers are heated to the required temperature by the Cartridge Heaters inserted into the individual Rollers. Adequate pressure is applied onto the Sealing Rollers so that both the foils get sealed at the time of contact while passing through the sealing roller. At this stage the product which is released onto the cavity of the rollers gets packed and sealed in the foils. Batch Coding Unit: The left hand Foil before being drawn by the Sealing Rollers passes through the Batch Coding unit where the Batch Code, Manufacturing date etc. is printed on the Foil.

Batch coding unit:

The left hand foil before being drawn by the sealing rollers passes through the batch coding unit where the batch code, manufacturing date etc is printed on the foil.

Cutting System:

The Packed and sealed Strip from the Sealing Roller passes through the Brush and Slitter Shaft which cuts the Strips vertically. These vertically cut strips then passes through the Cam operated Cutter Assembly which Cuts the Strips Horizontally into the desired Strip Length. The desired Strip Length can be achieved by using the appropriate Cutting Gears and Toe Cams as per the pre defined Calculations

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol Cum Report
- IQ Protocol cum Report
- Draft SOP for operating & Cleaning of Strip Packing Machine.
- Draft SOP for Preventive Maintenance of Strip Packing Machine.
- Electrical circuits diagram
- Technical specification of equipment

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 OQ 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 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	Draft SOP for Operation & Cleaning of STP.				
4.	Draft SOP for Preventive Maintenance of STP.				

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign / Date: ……

8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment / Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment / Instruments Name	Equipment / Instrument I.D.	Calibration On	Due On	Observed By Sign / Date

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign / Date: ……

8.3 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign / Date: ……

8.4 EMERGENCY OPERATION VERIFICATION:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
ON/OFF Push button • Press Stop Push Button.	Equipment should Stop		
• Release ON Push Button.	Equipment should Start		
With the Emergency Stop Pressed in, in Try to cause movement of an Operating function.	The Equipment will be inoperative		
Explosion Flap	To control excess pressure process immediately		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign / Date: ……

8.5 OPERATIONAL TEST

8.5.1 Control Panel Testing

Purpose:

To verify that the response of the equipment at the input from various Pushbutton / Switches on Control panel is as per the system design.

Procedure:

Give inputs from various Push buttons & Switches on Control Panel & observe the Response from the machine.

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Acceptance Criteria:

Input	Target	Observation	Observed By (Engineering) Sign/Date
Controls Panels main switch when Turned to the “ON" position.	Red light on the Control Panel indicating Mains will Glow.		
Vibrator ON/OFF switch when turned to the "ON" position.	Vibrator starts to function.		
Dimerstat of the Vibrator when rotated.	When the Dimerstat is rotated in the clock wise direction then the Vibration on the Vibrator will Increase and Visa-Versa when the Dimerstat is rotated in the anti clock wise direction the Vibration on the Vibrator will decrease.		
Heater ON/OFF switch when turned to the ‘ON’ position.	Both the Temperature Controllers will switch on and both the Heaters will start to		

Input	Target	Observation	Observed By (Engineering) Sign/Date
	heat and will attain the desired Temperature as set on the Temperature Controller. The Amp. Meter will indicate the Amp. rating of each heater and can also be used as an indicator to indicate whether the Heaters are in working condition or whether any of the Heater is Blown OFF.		
Machine lamp ON/ OFF switch turned to the 'ON' position.	Machine Lamp fitted inside the Machine will Glow.		
Green Push Button when Engaged.	When the machine is in idle condition and the Green Push Button is engaged the machine will start to function. (It functions as a START Mode)		
Yellow Push Button when Engaged.	As long as the Yellow Push Button is engaged the Machine will function but the push button is released the Machine will stop to function (It function as an INCH mode.)		
Red Push Button when Engaged.	When the Machine is in running condition and the Red Push Button is engaged the		

Input	Target	Observation	Observed By (Engineering) Sign/Date
	Machine cease to function. (It functions as a STOP Mode)		
Speed Variation screw of the VFD situated on the Control Panel when rotated.	When the Machine is in running condition (i.e. START Mode) if the Speed Variation screw is turned in the Clock Wise direction then the Speed of the Machine will increase. Likewise when the Speed Variation screw in turned in the Anti-Clock Wise direction then the Speed of the Machine will decrease.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign / Date: ……

9.0 REFERENCES:

The Principle Reference is the following:

- Master Validation Plan.
- Schedule – M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.

The following references are used to give addition guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition / March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, Beta. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.

10.0 DOCUMENTS TO BE ATTACHED:

- Operation And Maintenance Manual
- Copy of Draft SOP's
- Any Other Relevant Documents

11.0 DEVIATION FROM PREDEFINED 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:

No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
mm	:	Millimeter
Amp.	:	Ampere
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
STP	:	Strip Packing Machine

17.0 POST 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)			