DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

STRIP PACKING MACHINE

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

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

PROTOCOL CONTENTS

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

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)			

2.0 OBJECTIVE:

- To prepare the Design Qualification document for Strip Packing Machine 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 **Strip Packing Machine**.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's 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, Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Post Approval 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. • Post Approval of Qualification Protocol cum Report after Execution
Engineering	• Review of the 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 Process Description ➢ Safety Features and Alarms • Post Approval of Qualification Protocol after Execution.

5.0 BRIEF PROCESS 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.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification. 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
Application: The Strip Packing Machine should be able to Pack the Tablet/Capsule	Strip Packing Machine should meet the requirement for Packing of Tablet & Capsule.	Process Requirement
Working: Working of Strip Packing Machine	The Strip Packing Machine should be able to perform Packing of Tablet & Capsule using aluminum foils of 0.04 or 0.03 mm with hot sealing.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITIY REQUIREMENTS / LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	3 Phase Voltage- 415 V Frequency- 50 ± 3% Hz (To be assured by Engineering Department)	cGMP Requirement
Room Condition	Temperature: NMT 25^0C RH : NMT 22%	Process Requirement

7.3 TECHNICAL SPECIFICATIONS:

NAME OF COMPONENT	DESCRIPTION	REFERENCE
Equipment	Sharma Engineering Works	User Requirement
TYPE	Centre Electromagnetic Vibrator Feeding. M.S. fabricated body with adequate inspection windows, painted to pale cream to smooth finish. Hopper mounted on Telescopic adjustable stand made of S.S. Cladding all over the body of the machine of S.S.304 and all contact parts of S.S. 316 only	GMP Requirement
Overall dimensions	W 600 mm x D 1220 mm x H 2000 mm	Design Requirement
Drive	0.75 H.P. 3 ph. 415 V. 1385 R.P.M./TEFC Electrical motor (Remi Make) Oil immersed Reduction Gear Box., Universal Mounting Type (Bonfiglioli Make).Variable Frequency Drive-VFD (Mitsubishi Make) for speed variation.cam operated cutter assembly with spring loaded brake belt. Set of draw brushes fitted on brush shaft to draw out sealed strip from rollers with vertical slitters fitted on slitter shaft to slit sealed strip.	GMP Requirement
Heater	Cartridge Heaters for heating sealing rollers as per our catalogue specifications. Temperature is controlled by 2 sets of Digital Electronic Temperature Controller (Selectron make) to control both sealing rollers.	GMP Requirement
Temperature Controller	Make : Thermotech	GMP Requirement
Heating Controller	Sr. No. : 10-02 Model : TC 203AX Class : 1.5	GMP Requirement

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NAME OF COMPONENT	DESCRIPTION	REFERENCE
S.S. Packing Material Holder Assembly	2 sets of front adjustable type of friction brake system with foil running tube.	Design Requirement
ON/OFF Switch	Make : Tecknic 2LHBR-230	GMP Requirement
Green Push Button	Make : Tecknic With one light laminar	GMP Requirement
Red Push Button	Make : Tecknic Without light.	GMP Requirement
Yellow Push Button	Make : Tecknic Without light.	GMP Requirement
Red Emergency Stop Push Button	Make : Tecknic Type : Mushroom Head	GMP Requirement
Special Electrical Control Panel of S.S. consisting of:	"ON", "OFF", "INCH" controls and extra "INCH" Control near Clutch handle. DOL Air Brake contactor for heater, Amp Meter for heater, Indication lamps and MCB's and Digital Counter cum Speed indicator to indicate the speed	cGMP Requirement
Batch Coding Unit	Ceramic Roller type, nylon stereo rings or flat stereo drum mounted on bracket	cGMP Requirement
Polycarbonate Cabinet	Cabinet mounting on S.S. angles & S.S. frames for protection of Sealing Rollers, Brush Shaft & Cutter Assembly.	cGMP Requirement

7.4 TECHNICAL SPECIFICATIONS OF COMPONENTS AND SUB COMPONENTS USED/ BROUGHT BY MANUFACTURING

DESCRIPTION	SPECIFICATION	REFERENCE
Calibration	All components that require calibration shall be identified and calibrated. Calibration certificates to be provided. Test certificates / calibration charts of TIC to be provided.	cGMP Requirement
Qualifications/ Documentation	The manufacturer shall complete and provide the documents pertaining to Design, Installation & Operation Qualification. Information on purchased/bought-out parts. Circuits Diagram.	cGMP Requirement
Safety features	Adequate safety features for men and material shall be provided along with the equipment.	cGMP Requirement
Electrical system	The electrical system of the equipment shall be housed with adequate safety features. Electrical panel is to be installed on the Machine.	cGMP Requirement
Material of construction	M.S. fabricated body with adequate inspection windows, painted to pale cream to smooth finish. S. S. Cladding all over the body of the machine of S.S. 304 with matt finish. All the contact parts will be of S.S. 316. Material test certificates to be provided	cGMP Requirement

7.5 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of Construction
1.	All Contact Parts. a) SS Hopper. b) Chute	SS Sheet 18 swg of SS 316.
2.	Non Contact Parts. a) S.S Cladding. b) Control Panel. c) Side covers.	 SS Sheet 18swg of SS 304. SS Sheet 18swg of SS 304. SS Sheet 18swg of SS 304.
3.	M.S Parts. Batch Printing Bracket and Cutter parts.	M.S with Powder Coating / Plating.
4.	Front guard.	Polycarbonate-10mm thick.
5.	Draw Brushes.	Goat Hair (Not Food Grade) the brushes do not come in contact with the tablets.
6.	Gasket.	Gasket on covers not food grade.

7.6 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
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
Earth safety relay	If improper earthing halts the process	Safety Requirement
Emergency Switch	Should be provided at approachable distance	Safety Requirement
Motor overload relay	If overload the switchgear trip.	Safety Requirement
Temp. sensor air Inlet	If inlet temp. increases than set value, the steam control valve closes.	Safety Requirement
Explosion flap	If released relieves the excess pressure developed during explosion.	Safety Requirement
Air Pressure	If Air Pressure lower than required, than stops the process.	Safety Requirement

7.7 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for supplying the Strip Packing Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feed back 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 Strip Packing Machine.

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- 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
QA	:	Quality Assurance
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature circuit breaker
db	:	Decibel
C.I.	:	Cast Iron
RH	:	Relative Humidity
STD	:	Standard
MMI	:	Man Machine Interface
STP	:	Strip Packing Machine
SS	:	Stainless Steel
STP	:	Strip packing machine

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			