INSTALLATION VERIFICATION PROTOCOL CUM REPORT FOR SWING CONVEYOR

SUPERSEDES PROTOCOL No.	NIL
LOCATION	Ampoule Filling and Sealing Room

PHARMA DEVILS	INSTALLATION VERIFICATION PROTOCOL CUM REPORT FOR SWING CONVEYOR	PROTOCOL No.:

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PHARMA DEVILS	INSTALLATION VERIFICATION PROTOCOL CUM REPORT FOR SWING CONVEYOR	PROTOCOL No.:

1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence for the Installation verification of swing conveyor in Ampoule Filling Machine for transfer the Ampoule from Filling room to Ampoule hold room.
- To Provide Documented Verification that the Equipment as connected with ancillary system is suitable for indented purpose and produced product as per pre-defined Acceptance Criteria.

3.0 SCOPE:

- The scope of this installation verification protocol cum report is limited to installation verification of swing conveyor in Ampoule Filling Machine.

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, Review and Approval and Compilation of the Installation verification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation verification. • Monitoring of Installation verification activity.
Production	• Review of Installation verification Protocol cum Report. • To Co-ordinate and support for Execution of Installation verification study as per Protocol.
Engineering	• Review of Installation verification Protocol cum Report. • Co-ordination and technical support in Installation verification Activity. • Responsible for Trouble Shooting (if occurs during execution).

5.0 EQUIPMENT DETAILS:

Equipment Name	Ampoule Filling and Sealing Machine
Equipment ID.	
Model	
Manufacturer's Name	
Supplier's Name	
Location of Installation	Ampoule Filling and Sealing Room

6.0 SYSTEM DESCRIPTION:

Ampoule Filling & Sealing Machine adopts linear intermittent for filling and sealing. The ampoules which come from sterilization and drying tunnel access to infeed Conveying Belt No. 1 via the connection board move to scroll No.2. The scroll will arrange out of order ampoules in separation status, it pushes the ampoules individually to the infeed star wheel No. 4, infeed star wheel No. 4 continuously conveys the ampoules to the walking beam No.5, and front walking beam No. 5 can change the continuous movement of ampoules to intermittent movement. The middle walking beam No. 6 can convey the ampoules in a stepping mode to the next station. Ampoule leaning part No. 7 is used for orientation in the static station. The 5 intermittent stations are listed below:

1) **Front Charging Station**
2) **Filling Station**
3) **Rear Charging Station**
4) **Preheating Station**
5) **Sealing Station**
6) **Conveyor from Sealing Station to Ampoule Hold Room**

Front Charging Station: The front charging station is set with nitrogen gas purging.

Filling Station: At the filling station, rotary piston pump consists of a piece of to-and fro rotary valve, a piece of movable piston rod and a piece of pump cylinder The rotary valve is on the upper side of Pump cylinder, and it connects with drive group of rotary valve via a stand- alone servo motor via ball Screw pair, lifting rod and connection rod. By to and fro movement, the liquid medicine is filled into ampoules by the filling pump.

Rear Charging Station: The rear charging station can be set as inert gas charging.

Preheating & Sealing Station: At the preheating station, ampoules are preheated by the nozzle of

LPG and Oxygen, and they spin automatically by the idler wheel. At the station of sealing, ampoules are softened by heat and sealed. The sealed ampoules are conveyed throughout feed star wheel to ampoule receiving tray.

Conveyor from Sealing Station to Ampoule Hold Room: The conveyor from sealing station to ampoule room is equipped with swing wheel.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 EQUIPMENT VERIFICATION:

Installation Checks	Acceptance Criteria	Observation	Method of Verification	Observed By (Production) Sign/Date
Identification of Equipment and its Major Components:				
To identify equipment name	Conveyor with swing wheel			
Visual Inspection of all components for physical damage	No any component should be physically damaged			

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

7.2 LOCATION SUITABILITY:

Installation Checks	Acceptance Criteria	Observation	Method of Verification	Observed By (Production) Sign/Date
Location	Ampoule Filling and Sealing Room			
Working Condition	The system should be capable of working efficiency in the ambient conditions.			
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance			

7.3 SAFETY CHECKS:

Installation Checks	Acceptance Criteria	Observation	Method of Verification	Observed By (Production) Sign/Date
Corners & edges	All corners shall be rounded & no sharp edges observed.			
Joints	Welding of joints without any welding burrs			
Leveling And Balancing	Equipment should be properly balanced & leveled			
Easy accessible	Accessible components provided.			
Easy to clean	Components shall be easy to clean.			

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

Inference:

……

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

7.4 SWING OPERATION OF CONVEYOR:

S.No.	Items	Acceptance criteria	Observation	Observed By (Production) (Sign/Date)
1.	Move the conveyor by swing wheel	Easily move the conveyor		
2.	Movement the person across the conveyor	Person should cross the conveyor without tilted		
3.	Rearrange the conveyor for ampoule movement through the conveyor and start the filling at minimum speed	Ampoule should travel without obstruct		
4.	Start the filling at maximum speed	Ampoule should travel without obstruct		

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

Inference:

……

……

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

8.0 REFERENCES:

The Principle Reference is the following:

- Operation, Cleaning and Intervention of Ampoule Filling & Sealing Machine.

9.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

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10.0 CHANGE CONTROL, IF ANY:

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

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12.0 CONCLUSION:

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13.0 RECOMMENDATION:

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14.0 ABBREVIATIONS:

CC	:	Change Control
ID.	:	Identification
Ltd.	:	Limited
No./Nos.	:	Number
PROD.	:	Production
Pvt.	:	Private
QA	:	Quality Assurance

15.0 PROTOCOL POST APPROVAL:

PHARMA DEVILS	INSTALLATION VERIFICATION PROTOCOL CUM REPORT FOR SWING CONVEYOR	PROTOCOL No.:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			