



PHARMA DEVILS

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
NFD SYSTEM**

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
NFD SYSTEM**

EQUIPMENT ID No.	
LOCATION	Tablet Inspection
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL CUM REPORT No.	NIL



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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 (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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2.0 OBJECTIVE:

- To provide a documented evidence for the Installation Qualification of NFD System.
- 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 NFD System (Make: A. S. Automations) to be installed in the Tablet inspection.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of NFD System.

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, authorization and compilation of the IQ protocol cum report.• Co-ordination with production and engineering to carryout installation qualification• Monitoring of Installation Qualification Activity.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Approval of Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• Co-ordination, Execution and technical support in NFD System IQ Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Qualification Protocol cum Report after Execution



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5.0 EQUIPMENT DETAILS:

Equipment Name	NFD System
Equipment
Manufacturer's Name	A. S. Automations
Model	GMP Model
Supplier's Name	A. S. Automations
Location of Installation	Tablet inspection

6.0 SYSTEM DESCRIPTION:

The NFD system is coupled with the strip-packing machine. The machine checks all the strips to ensure that it contains all the tablets, strips with even one empty pocket are rejected automatically. The NFD system is a step towards automating the packaging lines. Consequently it requires good material inputs. A badly maintained strip - packing machine with problems such as jerks during cutting or bending of the strips during cutting will degrade the performance of the NFD system. Proper care must be taken to ensure that the strip-packing machine runs as smoothly as possible. The NFD system does not take care of rejection due to puncture pockets, foil defects etc. These problems must be addressed at the root level. The NFD system is a stand-alone system and does not in any way affect the performance of the strip-packing machine.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Technical specification of equipment.
- Calibration certificate of components.
- 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:

Installation Checks	Acceptance Criteria	Observation (Complies/ non complies)	Observed by Sign & Date
Leveling	Should be properly balanced and leveled		
Place of Installation	Tablet Inspection		
Room Condition	Temperature : 15-25°C Operating Humidity : 40-55 %		
Illumination in area	NLT 300 Lux		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

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Sign & Date:

8.2 EQUIPMENT VERIFICATION:

Installation Checks	Acceptance Criteria	Observation (Complies/ non complies)	Observed by Sign & Date
Equipment	NFD System		
Model	GMP Model		

ELECTRICAL INSTALLATION:

Electricity	Voltage	230 V AC \pm 1%		
	UPS	1 kW		
	Frequency	60/50 Hz \pm 2% Earth		
Electrical connections have been provided and secured.	Should be provided & secured.			
All components in the panel are properly secured.	Should be properly secured.			
All terminals are tightened.	Should be tightened.			
Earthing connection to control panel & equipment.	Earthing connection to control panel & equipment should be provided.			

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8.3 INSTALLATION CHECKS:

Description	Acceptance criteria	Observation (Complies/ non complies)	Observed by Sign & Date
System condition	<ul style="list-style-type: none"> All the components must be undamaged. 		
Power supply and fuse	<ul style="list-style-type: none"> System should be connected to UPS. Check that power supply connections and fuses installed conform to the wiring diagram. 		
Lighting	<ul style="list-style-type: none"> All LEDs in the illumination unit must light up. Visually inspect all the LED's light up and the inspection area is fully illuminated. 		
Assessment of installation quality	<ul style="list-style-type: none"> The installation conforms to the wiring diagram. All components are satisfactorily and/or properly connected and connections are properly labeled for identification. The installation has not resulted in any impairment or damage to the machine or the installed components. 		

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Sign & Date:

8.4 MOC VERIFICATION LIST:

Component	MOC	Observation (Complies/ non complies)	Observed by Sign & Date
NFD Control Panel	SS 304		
Mounting block of NFD system	Mild Steel		
Product sensing rollers	SS 304		
Rejection flappers	SS 304		
Rejection flapper mounting bracket	Mild Steel		
Strip guide cover on flappers	SS 304		
Strip guide cover on conveyor	SS 304		

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8.5 EQUIPMENT VERIFICATION

Name of The Component	Technical Specification		Observation (Complies/ non complies)	Observed by Sign & Date
	Make/Model	Specifications		
Control Panel Components				
PLC	MITSUBISHI / FX5U-64MFX5U Sr. No :- 1920166	Supply: 230VAC		
Input Extension Card	MITSUBISHI / FX5-8EX/ES Sr. No:-1990276	NA		
HMI	BEIJER /X2 BASE 7-F2 Sr. No :- 255881-01240	Supply: 24VDC		
Power Supply	MEANWELL/ SP-240-24	Input Supply: 230VAC Output Supply: 24VDC 10A		
	MEANWELL/ NES-25-5	Input Supply: 230VAC Output Supply: 5VDC 5A		
Power ON/OFF Switch	SALZER	Type: 2 Pole ON/OFF 6A		
NFD Card	A.S. Automations /ASA-2191205	Supply: 24 & 5VDC		
Universal sensing unit				
Universal NFD Sensors	PEPPERL+FUCHS / NBN4-12GM50-E2 Sr. No :-87767	Supply-30 VDC Type: Inductive PNP NO Non flush		
Sensing Roller Assembly	A.S. Automations	NA		
Support Rings	A.S Automations	NA		
Rejection Assembly				
Rejection Flappers	A. S. Automations			
Cylinders for Rejection Flapper	FESTO/ DSNU-10-25-P-A	Part No.: 19184 Stroke:25		
Solenoid Valve for Rejection Flapper	FESTO/ MSFG-24/42-50/60	Part No: 4527 Coil Supply: 24VDC,		
Air Pressure regulator	FESTO/ LR-D-MINI-M743	Part no:162591-M823		
Low air pressure switch	FESTO/ DE-73734	PART No: 8035549		



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Name of The Component	Technical Specification		Observation (Complies/ non complies)	Observed by Sign & Date
	Make/Model	Specifications		
Encoder Assembly				
Encoder	KUBLER/8.5020.885A.1024.0 050 Sr. No :-.....	Supply: 30VDC PPR: 1024		
Tablet Hold assembly				
Cylinder for Tablet Hold	FESTO/EGZ-16-10	Part no: 15045 stroke: 16 mm		
Solenoid valve for Tablet Hold	FESTO/ MSFG-24/42-50/60	Part No: 4527 Coil Voltage: 24VDC		

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Sign & Date:

8.6 ALARMS SYSTEM:

Points	Required for	Indication	Observation (Complies/ non complies)	Observed by Sign & Date
Low Air Pressure	when air pressure goes below operational level	1. Buzzer Indication 2. Alarm name in alarm screen as "LOW AIR PRESSURE DETECTED"		
NFD Bypass	When NFD Mode is in Manual Accept mode	1. Buzzer Indication 2. Alarm name in alarm screen as "MANUAL ACCEPT MODE ON"		
	When NFD Mode is in Manual Reject mode	1. Buzzer Indication 2. Alarm name in alarm screen as "MANUAL REJECT MODE ON"		
Print Rejection	Dry print occurs due to machine stop for set time period entered in HMI	1. Alarm name in alarm screen as "PRINT REJECTION DETECTED" 2. Tablets will be stopped		
Sealing Rejection	Burn tablets occurs due to machine stop for set time period entered in HMI	1. Alarm name in alarm screen as "SEALING REJECTION DETECTED" 2. Strips get rejected		

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8.7 SAFETY:

Checks	Acceptance Criteria	Observation (Complies/ non complies)	Observed by Sign & Date
Electrical wiring	Electrical wiring should be as per approved drawings.		
Start On/Off switch: To stop the process immediately	Should be provided For equipment and operator safety		
MCB for electrical overload	Should be properly installed		

Checked By
Sign & Date:

Verified By
Sign & Date:

Inference:

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.....
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Reviewed By
Sign & Date:

9.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan
- Schedule-M – “Good Manufacturing Practices and Requirements of Premises.
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.

10.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant documents.

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:

AC	:	Alternating Current
NFD	:	No fill detector
cGMP	:	Current Good Manufacturing Practice
DC	:	Direct Current
Kg	:	Kilogram
Ltd.	:	Limited
mm	:	Millimeter
MOC	:	Material of Construction
PLC	:	Programmable Logic Controller
QA	:	Quality Assurance
SS	:	Stainless Steel
Pvt.	:	Private
Ltd.	:	Limited
DQ	:	Design qualification
GMP	:	Current Good Manufacturing Practice
URS	:	User requirement specification
IR	:	Infrared
HMI	:	Human machine interference
CM	:	Centimeter
V	:	Volt



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17.0 PROTOCOL POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			