



**PHARMA DEVILS**

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

**PROTOCOL No.:**

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

<b>DATE OF QUALIFICATION</b>	
<b>LOCATION</b>	<b>Tablet inspection</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 (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

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



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**2.0 OBJECTIVE:**

- To prepare the Design Qualification document for NFD System on the 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 the designing of equipment and are properly documented.

**3.0 SCOPE:**

- The Scope of this Qualification Document is limited to the Design Qualification of **NFD System**.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.



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**4.0 RESPONSIBILITY:**

The Validation Group, comprising of representatives 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 of the Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.</li><li>• Review of Qualification Protocol cum Report after Execution.</li><li>• Co-ordination with Production and Engineering to carryout Design Qualification.</li><li>• Monitoring of Design Qualification Activity.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Approval of the Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.</li><li>• Review of Qualification Protocol cum Report after Execution</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of the Protocol cum Report.</li><li>• Assist in the Preparation of the Protocol cum Report.</li><li>• To co-ordinate and support the Activity.</li><li>• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none"><li>➤ Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures.</li><li>➤ Details of utilities</li><li>➤ Identification of components for calibration</li><li>➤ Material of construction of all components</li><li>➤ Brief Process Description</li><li>➤ Safety Features and Alarms</li></ul></li><li>• Review of Qualification Protocol after Execution.</li></ul>



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**5.0 BRIEF EQUIPMENT 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.

**6.0 EQUIPMENT SPECIFICATION:**

Equipment Specifications are based on User Requirement Specification. The manufacturer of equipment ensures complies with User Requirement Specification.

Critical Variables	Acceptance Criteria	Reference
Capacity	Sensing: max 14 tacks Flappers: Max 7 track	Process Requirement
Detection criteria	Tablets with thickness Min. 2.5mm and above, Only empty Pockets will be detected. That means system will not detect half tablet and broken tablets. System is suitable up to two toe products. (For 4 toe products the NFD is not suitable)	Process Requirement
Speed	60 cuts/ min for single Toe	Process Requirement
<b>Process; Mechanical sensing Unit:</b>	Tablets/Capsules are sensed after sealing process. Hence the sensing unit position is just below sealing roller. Mechanical sensing unit consist of Sensing roller assembly for each track/cavity and support rings. Whenever cavity with filled tablets/capsule passes from sensing roller it push SS roller back and SS strip attached to roller get deflected. The inductive sensor below the SS strip senses the deflection and sends an electrical signal to PLC. Support rings required to set at Knurling positions act as support for strip web to get desired deflection during sensing. Thus to check the tablets in each cavity we have to set a sensing roller assembly and support rings.	Process Requirement



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<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Reference</b>
<b>IR Channel Sensing Module:</b>	In this case Tablets /capsules are sensed in feeding channel before sealing process. IR module having IR transmitters and receiver sensors is mounted on the feeding channel at tablet releasing position. When tablets/capsules released through the feeding channel IR beam passing from transmitter to receiver get interrupted and this condition will be treated as presence of tablet by PLC.	Process Requirement
<b>Rejection assembly:</b>	The scanned strips from both sensing units are sorted out by rejection assembly. Good strips it is guided to fall on conveyor to transfer for next process. Reject strips are guided to fall in rejection bin. So to rejection flapper will work as guide for strips to fall in accept side and reject side. Rejection flappers are operated by pneumatic cylinders. PLC will sends signal to Solenoid valve to operate the cylinders according to strip status.	Process Requirement
<b>Encoder assembly:</b>	1024 PPR Encoder is mounted on the cutting shaft of machine. It will send the strip position signals to PLC in the form of pluses.	Process Requirement
<b>Provisions:</b>	Additional provisions such as Printing rejection (In case of dry print-Time Based), Sealing rejection (In case of Burnt tablet- Time based), and tablet hold are incorporated in the NFD system. Buzzer indication for empty detection	Process Requirement
<b>Alarms and Indications</b>	<ul style="list-style-type: none"><li>• Low air pressure and NFD bypass alarm.</li><li>• Buzzer indication for empty detection and alarm indication.</li></ul>	Process Requirement
<b>HMI Interface</b>	<ul style="list-style-type: none"><li>• Required to change the NFD parameter to operate the NFD system for different products. HMI interface is given to edit NFD parameters, Monitor the status of NFD system, View Alarm messages, Production Counter.</li><li>• HMI parameter editing is 3 level password protected (Operator/Supervisor/Admin)</li></ul>	Process Requirement
<b>Electrical Control Panel</b>	The system should have Electrical Control Panel.	Design Requirement



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**7.0 CRITICAL VARIABLES TO BE MET:**

**7.1 EQUIPMENT PARAMETERS:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Reference</b>
<b>SPECIFICATIONS</b>		
Min. Sensing thickness of tablet	2.5 mm.	Process Requirement
Sensing speed	Max. 55 cuts / Min. for single Toe cam tested	Process Requirement
Type of sensor	Mechanical Profile sensing arrangement.	Process Requirement
Horizontal Sensing Pitch	18 mm typically	Process Requirement
No. of tracks configurable	14 track (i.e. 07 strips per cut).	Process Requirement
Rejection of strips	Universal structure. Rejection flapper size will be of 35 mm width	Process Requirement
Toe Cam configurable with NFD	Single & Double only. Physician sample products with three & four Toe Cam are not suitable for NFD operation	Process Requirement
Hardware	Mitsubishi FX5U series PLC with touch screen HMI.	Process Requirement
Gap between cutter & delivery conveyor	220 mm. For extra-long strip sizes, this gap should be more.	Process Requirement

**7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Reference</b>
Utility connections should be available as per the manufacturer's specification.		
<b>Electrical Supply</b>	Phase : Single Phase Voltage : 230V Frequency : 50 Hz	cGMP Requirement
<b>Pneumatic</b>	Air pressure 4-6 Kg/cm <sup>2</sup>	Process Requirement





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**7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:**

**Control Panel Components**

S. No.	Items	Make/Model	Specifications	Qty.
1.	PLC	mitsubishi / FX5U- 64MFX5U Sr. No :- .....	Supply: 230VAC	1 No
2.	Input Extension Card	MITSUBISHI / FX5-8EX/ES Sr. No:-.....	NA	1 No
3.	HMI	BEIJER /X2 BASE 7-F2 Sr. No :- .....	Supply: 24VDC	1 No
4.	Power Supply	MEANWELL/ SP-240-24	Input Supply: 230VAC Output Supply: 24VDC10A	1 No
		MEANWELL/ NES-25-5	Input Supply: 230VAC Output Supply: 5VDC 5A	1 No
5.	Power ON/OFF Switch	SALZER	Type: 2 Pole ON/OFF 6A	1 No
6.	NFD Card	A.S. Automations /ASA-2191205	Supply: 24 & 5VDC	1 No

**Universal sensing unit**

7.	Universal NFD Sensors	PEPPERL+FUCHS / NBN4-12GM50-E2 Sr. No :-.....	Supply-30VDC Type: Inductive PNP NO Non flush	14 No.
8.	Sensing Roller Assembly	A.S. Automations	NA	14 No.
9.	Support Rings	A.S Automations	NA	15 No.

**Rejection Assembly**

10.	Rejection Flappers	A. S. Automations		7 No.
11.	Cylinders for Rejection Flapper	FESTO/ DSNU - 10 - 25 - P - A	Part No.: 19184 Stroke:25	7 No
12.	Solenoid Valve for Rejection Flapper	FESTO/ MSFG-24/42-50/60	Part No: 4527 Coil Supply: 24VDC,	7 No
13.	Air Pressure regulator	FESTO/ LR-D-MINI-M743	Part no:162591-M823	1 No
14.	Low air pressure switch	FESTO/ DE-73734	PART No: 8035545	1 No

**Encoder Assembly**

15.	Encoder	KUBLER/8.5020.885A.1024.0050 Sr. No :-.....	Supply: 30VDC PPR: 1024	1 No.
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**Tablet Hold assembly**

16.	Cylinder for Tablet Hold	FESTO/EGZ-16-10	Part no: 15045 stroke: 16 mm	1 No.
17.	Solenoid valve for Tablet Hold	FESTO/ MSFG-24/42-50/60	Part No: 4527 Coil Voltage: 24VDC	1 No.



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**7.4 MATERIAL OF CONSTRUCTION:**

Machine Parts	Acceptance Criteria	Reference
NFD Control Panel	SS 304 with Matt polished surface.	GMP Requirement
Mounting block of NFD system	Mild Steel with ENP plating	GMP Requirement
Product sensing rollers	SS 304	GMP Requirement
Rejection flappers	SS 304	GMP Requirement
Rejection flapper mounting bracket	Mild Steel	GMP Requirement
Strip guide cover on flappers	SS 304	GMP Requirement
Strip guide cover on conveyor	SS 304	GMP Requirement

**7.5 SAFETY:**

Critical Variables	Acceptance Criteria	Reference
<b>Electrical component</b>	The entire electrical components attached to high voltage are enclosed in a proper covering.	Safety Requirement
<b>Earthing</b>	Components enclosed in a cabinet to provide safety from live part and are properly earthen.	Safety Requirement
<b>Electricity supply</b>	Safety interlock, switch, sensor provided operates with 24 V DC supply.	Safety Requirement

**7.6 ALARMS SYSTEM:**

S.No	Points	Required for	Indication	Reference
1.	Low Air Pressure	when air pressure goes below operational level	1. Buzzer Indication 2. Alarm name in alarm screen as "LOW AIR PRESSURE DETECTED"	Process Requirement
2.	NFD Bypass	When NFD Mode is in <b>Manual Accept</b> mode	1. Buzzer Indication 2. Alarm name in alarm screen as "MANUAL ACCEPT MODE ON"	Process Requirement
		When NFD Mode is in <b>Manual Reject</b> mode	1. Buzzer Indication 2. Alarm name in alarm screen as "MANUAL REJECT MODE ON"	Process Requirement
3.	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	Process Requirement
4.	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	Process Requirement



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**7.7 VENDOR SELECTION:**

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the NFD System	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/ financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

**Verified By**  
**Sign & Date:** .....

**8.0 DOCUMENTS TO BE ATTACHED:**

- 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:**

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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**13.0 REVIEWED BY:**

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

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

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