



PHARMA DEVILS

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

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1.0 OBJECTIVE:

To design, engineer, and supply the (NFD systems) as per cGMP and cGEP guidelines and to provide assurance that the machine is manufactured as per the URS and it complies with the Scope of Supply.

To prove that each operation proceeds as per the design specification and the tolerances prescribed there in the document, are the same at utmost transparency. Validation procedure is set for complete satisfaction of the customer & building confidence of the user about the machine.

2.0 SCOPE:

The scope of this qualification document is limited to the Design Qualification of NFD system. This qualification document is part of a validation activity for the NFD system

Qualification of support utilities is not within the scope of this qualification document.

The equipment shall be used for empty pocket detection strips. The equipment shall operate under dust free environment and conditions as per the GMP requirements.

3.0 RESPONSIBILITIES:

CLIENT:

1. To provide the URS for the equipment.
2. To perform the Factory Acceptance Test (FAT).

MANUFACTURER:

1. To design, engineer and provide the complete technical details of the equipment pertaining to its design qualification viz.
 - (i) Machine overview,
 - (ii) Equipment orientation with layout,
 - (iii) Specifications of the sub-components/bought out items, and their make, model & quantity, and backup records/brochures,
 - (iv) Details of Utilities,
 - (v) Identification of components for calibration
 - (vi) Material of construction of all components
 - (vii) Brief process description
 - (viii) Safety features and alarms
 - (ix) Pre-installation requirements



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2. To facilitate the client for the Factory acceptance test of the machine at their works/ site.
3. To confirm the safe delivery of the equipment to the user site.
4. To ensure that no un-authorized and/or unrecorded design modifications shall take place. If at any point in time, any change is desired in the mutually agreed design, Change control procedure shall be followed and documented.
5. To ensure the proper installation and commissioning of the equipment.

4.0 USER REQUIREMENTS SPECIFICATION (URS):

DESCRIPTION	SPECIFICATIONS
Equipment	Channel Sensing NFD system
Specification	As per Annexure to Purchase Order.
Operating speed	60 cuts per minute.
Model	<ul style="list-style-type: none">• Parts of the NFD shall be of SS304/backlight.• The equipment should be a easy to clean
Process	Equipment should be able to detect and separate strips with a missing tablet.
Material of construction	All the contact parts of the NFD shall be either of SS 304/Mild Steel
Qualifications/ Documentation	<ul style="list-style-type: none">• The manufacturer shall complete and provide the documents pertaining to Design, Installation & Operation Qualification and detail functional specifications including control system with screen design of operating terminal.• Alarms• Circuits details.
Safety features	Adequate safety features for men and material shall be provided along with the equipment.
Control system	The equipment shall be controlled through PLC-based system.
Electrical system	The electrical system of the equipment shall be housed as per the cGMP and cGEP standard, with adequate safety.



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5.0 MACHINE 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 machine and does not in any way affect the performance of the strip-packing machine.

6.0 TECHNICAL SPECIFICATIONS:

As per annexure to order.

**7.0 TECHNICAL SPECIFICATIONS OF COMPONENTS & SUB - COMPONENTS
USED/BOUGHT OUTS**

COMPONENT	MAKE	MODEL/PART No.	SPECIFICATION	QTY.
PLC	mitsubishi	FX3U-48MT	Inputs:24 no Outputs:24 No Supply: 230VAC-50Hz	1
Input Extension Card	mitsubishi	FX2N-8EX	Inputs:08 no	1
POWER SUPPLY 24VDC	MEANWELL	SP 240-24	Supply:230VAC-50HZ Output:24VDC-10A	1
POWER SUPPLY 12VDC	MEANWELL		Supply:230VAC-50HZ Output:12VDC	1
POWER SUPPLY 5VDC	MEANWELL		Supply:230VAC-50HZ Output:5VDC	1
Single position on/off switch with NO element	IDEC	YW-E10	Supply:24VDC	1
ENCODER	KUBLER	8.5020.885A.0360.0030	Supply:24VDC PPR:360	1
Mechanical type NFD sensors	PEPPERL+FUCHS	NBN4-12GM50-E2	Type: Inductive Size: M12 –PNPNO-NON flush Supply:24VDC	12
Channel type NFD sensors		TIL 78-Receiver TIL 32-Transmitter	3mm LED IR sensor pair	12 (max)
Foil Joint sensors For Left & Right side	DATALOGIC	S8-PR-5-W03-PP	Type: Contrast RGB PNP NO 24VDC	02
NFD card PCB	A S Automations	ASA2100244	16 Channel	1
Buffer card PCB1	A S Automations	ASA2130132	8 Channel	1
Buffer card PCB2	A S Automations	ASA2130133	4 Channel	1
Counting PCB	A S Automations	ASA2090803	12 Channel	1
Transmitter check PCB	A S Automations	ASA2100335	16 Channel	1
NFD Buzzer	STEAM AIRTRIC	BZ-24ACDC-RED	Supply:24VDC	1



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COMPONENT	MAKE	MODEL/PART No.	SPECIFICATION	QTY.
		TYPE ECO		
HMI	EXOR	EV 058TST	Supply: 24VDC Screen Size: 5.7 Inch-touch	1
Relay	Omron	MY4N -DC24 3A 4PDT RELAY,	Supply: 24VDC 4 changeover	1
Relay terminal	Wago	859-3304	Supply coil:24VDC 1 changeover	7
Power on/off switch	SALZER	61002SAB13TDYR	5A- 2pole on/off switch	1
Solenoid valve For rejection	Festo	MFH -5- 1/8	Coil Voltage: 24VDC	6
Solenoid valve for tablet Hold	Festo	MFH- 3-1/8	Coil Voltage: 24VDC	1
Cylinders For rejection	Festo	DSN - 10 - 25 – P	--	6
Cylinders For tablet hold	Festo	EGZ - 16 -10	--	1
Regulator	Festo	LR - 1/4 - D – MINI	--	1
Low air pressure switch	Festo	SDE5-D10-O-Q6E-P-K	--	1
Sensing roller assembly	A S Automations	--	--	12
Support ring	A S automations	--	--	13
Rejection flappers	A S Automations	--	--	6
Sensitivity POT	100 Ω 3 W	Single Turn	1

8.0 DETAILS OF UTILITIES:

8.1 Single phase electric supply, approx 200 watts, 220V, 50Hz.

8.2 10 cfm compressed air at minimum 3kg/sq cm pressure.

9.0 MATERIAL OF CONSTRUCTION

S.No.	COMPONENT DESCRIPTION	MOC
1.	NFD Panel	SS 304
2.	Sensing Module	Backlight
3.	Rejection Arrangement	SS304/MS



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10.0 BRIEF PROCESS DESCRIPTION:

NFD System sections.

- I. Empty pocket detection and defective Strip rejection.
- II. Rejection System.
- III. Control panel.
- IV. Interlocks.

I. EMPTY POCKET DETECTION DEFECTIVE STRIP REJECTION: When a tablet is not released from the release pin, an empty pocket is generated. Hence for detecting empty pocket, a tablet is sensed after the release pin. For detecting a tablet one pair of sensors per track of the chute, on either side of the chute, are used. On one side there are Infrared (IR) transmitters which emit IR rays, these rays pass through the hole drilled in the track of the chute and fall on the receiver, which on the other side of the chute. Hence this transmitter - chute - receiver forms a beam. When a tablet is released from the release pin, it cuts this beam before falling in the pocket of the rollers. This signal is sent to the control panel (PLC). The transmitter sensors, receiver sensors and their mounting arrangement are called as the scanning head.

IV. REJECTION SYSTEM:

1. Flapper: - it is a metallic plate to guide the strips. There is a specific flapper number according to its position from machine wall side.
2. Numbering of flappers start from machine side.

There is an encoder which is mounted on the cutter shaft of the strip packing machine. This encoder serves as an interface between the strip machine and the NFD system. This encoder gives pulses to PLC. The total 360 pulses / revolution is the resolution of it. In relation to encoder, we need to set two positions in PLC program, one is strip start position which we called it as CLOCK. The other position is rejection flapper operating position. This is defined as FLAP in PLC program. Both these positions are to be set after every product change over.

V. CONTROL PANEL:

The control panel consists of the DC power supply of 24V DC for all control Components to function. The PLC needs 230V AC supply for its operation. The HMI needs 24V DC supply for its operation. All the tracks are individually Connected to PLC for their status reading. We need to load following data in HMI for different products.

- How many notches on CAM disc? - This is mentioned as no. of TOES.
- How many number of strip tracks are there? The system has max. no. of tracks as four. So as per change part kindly load this figure in 'No. of tracks'.
- The value entered is the indication of, how many tablets should sense the sensor in one strip. This is mentioned as No. OF SENSOR COUNT



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e.g. If Sensor Count = 05, then in each strip each sensor will sense the 5 tablets or capsules.

-The value entered in this represents number of columns assigned for each track (Strips) selected. This is mentioned as NO. COLUMN PER TRACK .

e.g. 'Columns/ Track: 2'. This will indicate each track consists two columns of tablets.

- How many strips are there between sensing roller and Cutter? - This is mentioned as no. of count from sensing roller to cutter. This is to counted manually or set automatically.

- What is the encoder position when the cutting position or strip end position is at the feeding channel end this is to be loaded as CLOCK position in HMI.

- What is the Flapper operating position? Flapper should operate when the strip is between the cutter & flapper. This position also to be loaded in HMI as FLAP.

- What is the encoder tablet holding position when the feeding channel is at the cutting position or in other words between two strips? This is to be loaded as TABLET HOLDING CLOCK position in HMI.

All above variables are called 'Parameters'. These can be changed to accommodate different products, different Strips layouts etc. Parameters, their meaning and their entry procedure are given in electrical manual. The parameter values are protected from Intentional / accidental change by a password system. Unless the correct password is fed, access to the parameter bank is denied. Each parameter has a lower and higher limit. If one tries to feed abnormal values, such as tracks as five, the PLC does not accept the value and shows the limit.

Additional provisions made in PLC programs:

1 Sealing Rejection: Similar provision is also provided for sealing. This interlock is important as when machine stops, the strip trapped in sealing roller gets damaged. So you can reject these damaged strips automatically.

For above provisions, following data is to be loaded in HMI.

No. of strips to be rejected:

No. of strip count from sealing to cutter:

Time of activation: In seconds

INTERLOCKS:

Printing Rejection Recovery:

When machine is kept off for one minute or more than one minute (time is adjustable), the Dry Ink Recovery is provided to hold the tablets whose strip printing is dried.

The details of Dry Ink Rejection are as follows.

No. of strips to be recover:

No of strips from printing station to feeding channel dropping end

Time of activation: In seconds



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Joint Detection Recovery

For foil joint detection separate sensors are provided. The following setting is required to recover the tablets joint detected strips.

The details of Joint Detection are as follows.

Reject Count- Decides how many strips are to be recovering before and after the joint.

No. of strips from joint sensor to feeding channel dropping end.

Manual Tablet Holding Switch

For operator easiness Manual tablet holding switch is provided.

Low Air pressure Interlock:

When pressure gets down from set point that time this interlock activates

11.0 SAFETY FEATURES AND ALARMS:

DIFFERENT FAULTS AND ACTIONS TO BE TAKEN

Different faults are indicated by PLC.

Fault No.	Fault	How to Check
1	Encoder Counting Stop	Check Encoder Counting (0 to 360) During machine run on Main screen of HMI
2	Low Air Pressure	Message will be triggered on HMI As "LOW AIR PRESSURE"
3	Sensor Fault	Check 1 to 12 numbers on control panel sensor Indications. If LED is off Continuously even if all tablets are present corresponding sensor is faulty.
4	NFD Bypass	Check Manual accept or reject switch

12.0 FAT PROCEDURE:

Factory Acceptance Test Procedure shall be as follows:

After the completion of erection work of the machine, client shall be informed to perform the factory acceptance test (FAT).

Client shall perform the FAT at the manufacturer site and record all the data in the prescribed FAT document as per the details given below:

1. Test criteria
2. Design Verification Check list
3. Deficiency & Corrective Action report



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4. Pre-installation requirements
5. Final report

13.0 CHANGE CONTROL PROCEDURE:

Change in the agreed design shall be addressed through the well-defined Change control procedure.

14.0 DESIGN QUALIFICATION REPORT APPROVAL

14.1 Summary:

14.2 Certification:



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15.0 APPENDIX

15.1 LIST OF ABBREVIATIONS

cGMP	current Good Manufacturing Practices
GEP	Good Engineering practices
AISI	American Iron & Steel Institute
MS	Mild steel
SS	Stainless Steel
CFM	Cubic Feet Per Minute
KW	Kilo Watt
DQ	Design Qualification
FAT	Factory acceptance test

15.2 REFERENCE DOCUMENTS

1. Manufactures Brochure (s) / Manual (s). (Title and Location).

To be supplied with the Installation qualification documents

1. Instruction & Maintenance manual

2. Material of construction certificates

2. Purchase Order Attached (Yes / No). If no, state Location.

Remarks (if any) :



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15.3 ANNEXURE LIST

S.No.	DESCRIPTION	ANNEXURE No.
1.	Equipment Brochure	
2.	Purchase Order (Including Annexure to Purchase Order - I, II & III)	
3.	Circuit Diagram - control panel	