



PHARMA DEVILS

**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

TABLE OF CONTENT

1. Objective
2. Scope
3. Responsibility (Client and manufacturer)
4. Machine description
5. Validation Requirement
 - 5.1 IQ Requirement
 - 5.2 OQ Requirement
6. Qualification Test Sheets.
7. Installation Qualification Tests
 - 7.1 Documents & Drawings Verification
 - 7.2 Verification of Technical Spec. for In-House & Bought out items.
 - 7.3 Utilities Verification
 - 7.4 Critical instrument Calibration Verification
 - 7.5 Installation Qualification Test Status
8. Operational Qualification Tests
 - 8.1 Verification of behaviour of m/c in normal case.
 - 8.2 Verification of behaviour of m/c in case of faults
9. Change control procedure
10. Qualification Document report approval
11. Appendix



PHARMA DEVILS

**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

1.0 OBJECTIVE:

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.

The objectives of the validation program are:

1. To provide record of the key features of the equipment and components as currently installed
2. To ensure that there is sufficient information available to enable the equipment to be operated and maintained safely, effectively and consistently.
3. To ensure equipment as installed
 - a) Meets the customer's specifications & requirements.
 - b) Complies with the Current Good Manufacturing Practices.
4. To test the operational aspects of the NFD, in customer's facility that are considered critical for satisfactory performance, and
5. To compare the results obtained with approved specification and customer's requirements.

2.0 SCOPE:

The scope of this qualification protocol is limited to the Installation and Operational Qualification of NFD system.

IQ/OQ

The validation will include the Operational Qualification of the NFD System, once the Installation Qualification of the equipment has been completed. Qualification activities will include the equipment and associated utilities.



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

3.0 RESPONSIBILITIES:

CLIENT:

1. To perform the Factory Acceptance test (FAT).
2. To perform the Site Acceptance test (SAT)

MANUFACTURER:

1. Machine overview
2. Installation Qualification Tests
3. Operational Qualification Tests

4.0 SYSTEM 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.

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 a 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



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

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.

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
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 strip 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.



PHARMA DEVILS

**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

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

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 recover 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

5.0 VALIDATION REQUIREMENTS:

5.1 IQ Requirements for-Universal NFD System.

The following requirement / practices apply to Universal NFD System activities:

- Verify that pre installation checks have been thoroughly done as per A S Automations Engineer`s pre installation checks document`s
- Verify that all rejections generated by strip packing machine (which will go directly in the market) other than those taken care of by NFD system, are within acceptable limits.
- Verify that systems are installed in accordance with approved engineering drawings and documents, which shall include the following (as applicable).
- Flow diagrams, isometric drawings, electrical & mechanical drawings, and P&IDs.



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

- Equipment and Installation specification; and
- Vendor drawings and equipment manuals
- Verify that the equipment and instrumentation are clearly described as per vendor, model, capacity, materials of construction and any critical criteria.
- Confirm that the NFD system is installed properly and that the documentation is available.
- Verify that major components are tagged or labelled.

5.2 OQ Requirements for NFD system.

The following requirement / practices apply to all OQ activities:

Verify that the NFD system, perform and operate in accordance with the client specification and requirements.

Review the preventive maintenance program and procedures to ensure that they are comprehensive and support continued, reliable performance of the equipment.

Verify that operating personnel are trained on the SOP's before being permitted to work on the equipment.



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

6.0 QUALIFICATION TEST SHEETS:

The Installation tests are specified according to the Validation Master Plan for NFD **SYSTEM** or each test (as applicable)

- Test number
- Rationale or purpose for test
- Test equipment to be used (if applicable)
- Procedure
- Acceptance criteria
- Results or data to be recorded
- Comments / Conclusions
- Reviewed by
- Clarification certificate verification (if applicable)



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

7.0 INSTALLATION QUALIFICATION TESTS:

The table below lists the tests to be performed as part of the Installation Qualification phase.

TEST NUMBER	CRITICAL FEATURE
7.1	Documents & Drawings Verification
7.2	Verification of Technical Specification for In-House & sub-components / bought out items
7.3	Utilities Verification

7.1 Documents & Drawings Verification

7.1.1 Rationale -

To verify that the documentation provides complete and correct technical references and permits servicing of the units.

7.1.2 Test equipment -

None Required.

7.1.3 Procedure -

1. Verify that the required documents and drawings listed in the tables below are available.

7.0 Installation Qualification Test: (Continued)

2. Review the documents and drawings for completeness and exactness with the installed units.

- Sign and date all copies of the drawings once verification is completed.
3. Attach the copies of the drawings to this protocol or reference the location from where they can be easily retrieved.



**INSTALLATION & OPERATIONAL QUALIFICATION
 PROTOCOL CUM REPORT
 FOR
 STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

4. Any items in the installation, which are not conforming to the corresponding drawings, must be commented on in the appropriate space. List the non-conformances and the reasons for them in an attachment if necessary.

7.1.4 Acceptance Criteria -

1. The documents must be accurate and complete.
2. The drawing information must correspond to the physical installation.

7.1.5 Documentation Verification Results.

Title	Document Number	Reference & Rev. Date	Location	Initial / Date mm/dd/yy	
Installation, Maintenance and Operation Manual					
Acceptance criteria Met? (Yes / No)					

7.0 Installation Qualification Test: (Continued)

9.1.6 Drawing Verification Results:

Title	Document Number	Reference & Rev. Date	Location	Initial / Date mm/dd/yy	
NFD system					
Acceptance criteria Met? (Yes / No)					



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

Test # 7.1 - Conclusions / Comments:

PASS

FAIL

Verified By: _____

Date: _____

Reviewed By: _____

Date: _____



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

7.0 Installation Qualification Test: (Continued)

7.2 Verification of Technical Specification for In-House & sub-components / Bought out items

7.2.1 Purpose

To verify that each major component of the NFD system are present and they are identified.

7.2.2 Test Equipment

None Required.

7.2.3 Procedure

1. Confirm that identification nameplates have been applied to the units and that these indicate the following (where applicable).
 - Type
 - Identification (Tag)
 - Manufacturer
 - Model Number
2. Confirm that the various components of NFD system are present and tagged as per specifications and drawings, in the proper number and configuration.
3. Record the method of verification (i.e. purchase order, equipment drawing, manual, packing slip, etc.)



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

7.0 Installation Qualification Test: (Continued)

4. Note any deviations or discrepancies and recommend follow up action if required.

7.2.4 Acceptance Criteria

All units and parts specified in design qualification and on latest revision of drawings must be present, documented and tagged.



**INSTALLATION & OPERATIONAL QUALIFICATION
 PROTOCOL CUM REPORT
 FOR
 STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

**7.2.5 Channel Sensing NFD System, Major Components Results
 7.2.6**

Description	Specification	Meets Spec. (Yes/No)	Verification Source	Initials	Date
1. Equipment Description					
Name	NFD system				
Specification	12 sensors, 6 tracks				
Capacity	1 - 6 Strips				
Model	Channel sensing NFD System				
Dimensions of control panel	480 x 430 x 220 mm				
Material					
Surface Finis	Stainless Steel 304		Supplier's certificate		
2. Control panel.					
Material	Matt Polished		Visual		
Surface Outside	Stainless Steel 304		Supplier's certificate		



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

Test # 7.2 - Conclusions / Comments:

PASS

FAIL

Verified By: _____

Date: _____

Reviewed By: _____

Date: _____



PHARMA DEVILS

**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

7.0 Installation Qualification Test: (Continued)

7.3 Utilities Verification

7.3.1 Rationale -

To verify that all necessary utilities are correctly installed.

7.3.2 Test equipment -

Calibrated digital multi-meter

7.3.3 Procedure -

1. Confirm that utilities connections are configured as per specification and in compliance with local codes.
2. Record the results in the table below. Note any deviations or discrepancies.

7.3.4 Acceptance Criteria

1. All services and connections must be installed and documented.



**INSTALLATION & OPERATIONAL QUALIFICATION
 PROTOCOL CUM REPORT
 FOR
 STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

7.0 Installation Qualification Test: (Continued)

7.3.5 Utilities Specification Results

Description	Specified	Measured Results	Meets. Spec. (Yes/No)	Initial / Date mm/dd/yy	
Electrical	Phase : 1 phase + Neutral + Earth 220V between Phase and Neutral. Frequency : 50 Hz.				
Compressed Air	Pressure: Min. 3 Kg/sq.cm, Max. 6 Kg/sq.cm. Flow Rate: 10 SCFM.				

7.3.6 Instrument Used

Test Instrument	Manufacturer	Identification Number ID	Calibrated Mm/dd/yy	Calibration Due Date	Initial / Date mm/dd/yy	
Multimeter						



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

7.0 Installation Qualification Test: (Continued)

Test # 7.3 - Conclusions / Comments:

PASS

FAIL

Verified By: _____

Date: _____

Reviewed By: _____

Date: _____



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

7.0 Installation Qualification Test: (Continued)

7.4 Critical Instrument Calibration Verification

7.4.1 Rationale -

To verify that all critical instruments for the, NFD System has been calibrated before starting the Operational Qualification.

7.4.2 Test equipment -

Calibrated Digital Multi Meter (or any other instrument).

7.4.3 Procedure -

1. Verify that all critical instruments are calibrated using an approved procedure, against a traceable standard.
2. Note any deviations or discrepancies and recommend follow up actions if required.
3. For all critical instruments, attach copies of calibration certificates to this protocol.

7.4.4 Acceptance Criteria

2. All critical instrumentation for the NFD system, shall be in a state of calibration.



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

7.4 Critical Instrument Calibration Verification (Continued)

No instrument used in NFD which needs calibration.

7.0 Installation Qualification Test: (Continued)

Test # 7.4 - Conclusions / Comments:

PASS

FAIL

Verified By: _____

Date: _____

Reviewed By: _____

Date: _____



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

7.0 Installation Qualification Test: (Continued)

7.5 Material of Construction Verification

7.5.1 Rationale -

To verify that all assembly of the NFD system has been manufactured in Stainless Steel as per the specification provided by the customer.

7.5.2 Test equipment -

MOC is to be verified as per certificates provided by manufacturer.

7.5.3 Procedure -

1. Identify part whose MOC is to be confirmed.
2. Match the part with certificate provided.

7.5.4 Acceptance Criteria

1. All material of construction for the NFD system , shall meet the MOC provided in Design Qualification.

7.5 Material of Construction Verification (Continued)

7.5.5 Material of Construction verification Results

Description	Specification	Meets Spec. (Yes/No)	Verification Source	Initials	Date
Rejection bracket	SS 304		Supplier's certificate		
Control Panel	SS 304		Supplier's certificate		
Pneumatics	Festo		Supplier's certificate		



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

7.0 Installation Qualification Test: (Continued)

Test # 7.5 - Conclusions / Comments:

PASS

FAIL

Verified By: _____

Date: _____

Reviewed By: _____

Date: _____



**INSTALLATION & OPERATIONAL QUALIFICATION
 PROTOCOL CUM REPORT
 FOR
 STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

7.0 Installation Qualification Test: (Continued)

7.6 Installation Qualification Tests Status

The table below lists the tests performed and related results.

Test Number	Critical Feature	Pass / Fail		Deviation Found	
		Pass	Fail	Yes	No
7.1	Documents & Drawings Verification				
7.2	Verification of Technical Specification for In-House & Sub-contract / bought out items.				
7.3	Utilities Verification				
7.4	Critical Instrument Calibration Verification				
7.5	Material of Construction Verification				

Description	Yes	No	Initials
			Date
All critical test/verification have been performed and acceptance criteria and/or major deviation completed before starting Operational Qualification.			



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

7.0 Installation Qualification Test:

Conclusions / Comments:

PASS

FAIL

Verified By: _____

Date: _____

Reviewed By: _____

Date: _____



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

8.0 Operational Qualification Tests

The table below lists the tests to be performed as part of the Operational Qualification phase.

TEST NUMBER	CRITICAL FEATURE
8.1	Testing of empty pocket detection and rejection, Burnt tablet rejection.
8.2	Testing of low air pressure interlock.
8.3	Testing of Printing rejection interlock
8.4	Testing of Joint Detection interlock
8.5	Testing of Manual Tablet holding interlock
8.6	Testing of NFD Bypass interlock



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

8.0 Operational Qualification Test (Continued)

8.1 Testing of empty pocket detection and rejection, Dry ink rejection, Burnt tablet rejection.

8.1.1 Rationale -

To verify functioning of empty pocket detection and rejection, Dry ink rejection, Burnt tablet rejection.

8.1.2 Test Equipment -

None required.

8.1.3.1 Procedure (Empty pocket detection and rejection)-

1. Ensure that NFD switch on control panel is in AUTO mode.
2. Start Strip Packing Machine with tablets.
3. Stop any one tablet from track number 1. (Nearest to the strip packing machine).
4. Repeat step no. 3 till you have succeeded in stopping first tablet in a row in a strip.
5. Repeat step no. 3 till you have succeeded in stopping last tablet in a row in a strip.

8.1.4.1 Acceptance Criteria -

All strips with empty pocket should get rejected.

8.0 Operational Qualification Test (Continued)

8.2 Testing of low air pressure interlock

Procedure: Ensure that the pressure switch is set.
Decrease the pressure from set point.

Acceptance criteria- strip packing machine will stop.

8.3 Procedure (Dry ink rejection)-

1. Ensure that dry ink rejection facility is on.
2. Run strip packing machine with tablets/capsules (as per the product)
3. Stop the machine sufficiently long (machine stop time entered in parameter) till ink on transfer roller\ stereotypes of printing unit dries.



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

5. Make a horizontal mark on the plain foil near the printing position to mark start of dried ink patch.
6. Start strip packing machine and run it without producing even a single empty pocket.

8.1.4.2 Acceptance criteria-

1. All the strips with mark should get rejected.

8.1.3.3 Procedure (Burnt tablet rejection)-

1. Ensure that burnt tablet rejection facility is on.
2. Run strip packing machine with tablets/capsules (as per the product)
3. Stop the machine for little longer than machine stop time entered in parameter to simulate burning of tablets in between rollers.
4. Put a piece of plain foil protruding out of rollers, in between rollers such that piece gets sealed with the foil and will serve as a mark of the tablet position which were burnt.
5. Start strip packing machine and run it without producing even a single empty pocket.

8.4 Procedure (Joint rejection)-

1. Ensure that joint rejection facility is on & the sensor is set.
2. Run strip packing machine with tablets/capsules (as per the product)
3. Stop the machine & place joint on foil.
6. Start strip packing machine and run it without producing even a single empty pocket.

8.1.4.2 Acceptance criteria-

1. All the strips with joint should get rejected.



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

8.0 Operational Qualification Test (Continued)

8.1.3.4 Procedure (Manual tablet holding switch rejection)-

1. Make a horizontal mark near stretching across foil width using a marker pen.
2. Run strip packing machine with tablets/capsules (as per the product) and run it without producing even a single empty pocket.
3. Press the Manual tablet holding switch as soon as the tablet is hold & empty pocket get rejected.

8.1.4.4 Acceptance criteria-

1. All the strips with mark should get rejected.

8.2 Testing of NFD Bypass interlock

Procedure: Ensure that the NFD System is Bypass
(Manual Accept Position or Reject Position)

Acceptance criteria- strip packing machine will stop.



**INSTALLATION & OPERATIONAL QUALIFICATION
 PROTOCOL CUM REPORT
 FOR
 STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

8.0 Operational Qualification Test: (Continued)

8.6 Operational Qualification Tests Status

The table below lists the tests performed and related results.

Test Number	Critical Feature	Pass / Fail		Deviation Found	
		Pass	Fail	Yes	No
8.1	Testing of empty pocket detection and rejection, Burnt tablet rejection.				
8.2	Testing low air pressures switch interlock.				
8.3	Testing of Printing rejection interlock				
8.4	Testing of Joint Detection interlock				
8.5	Testing of Manual Tablet holding interlock				
8.6	Testing of NFD Bypass interlock				

Description	Yes	No	Initials Date
All critical test/verification have been performed and acceptance criteria were met and/or major deviation completed.			



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

8.0 Operational Qualification Test:

Conclusions / Comments:

PASS

FAIL

Verified By: _____

Date: _____

Reviewed By: _____

Date: _____



**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

9.0 Change Control Procedure

Any changes or modifications to the equipment will be performed in accordance with the appropriate change control procedure. A separate assessment will be made if any changes or modifications are requested and to whether relevant re-qualification action steps are required.

10.0 Qualification Document Report Approval

10.1 Summary:

10.2 Certification:



PHARMA DEVILS

**INSTALLATION & OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACK CHANNEL SENSING NFD SYSTEM**

PROTOCOL No.:

11.0 Appendix

11.1 List of Abbreviations

SAT	Site Acceptance Tests
FAT	Factory Acceptance Tests
CGMP	Current Good Manufacturing Practice
IQ	Installation Qualification
N/ Ap	Not Applicable
N/ Av	Not Available
OQ	Operational Qualification
P&ID	Piping and Instrumentation Diagram
REV	Revision
PQ	Performance Qualification
Spec.	Specification
PLC	Programmable Logic Controller
CPU	Central Processing Unit
HMI/MMI	Human / Man Machine Interface
SOP	Standard Operating Procedure

11.2 Units of Measure

HP	Horsepower
Rpm	Revolution Per Minute
Psi	Pounds per square inch.
Kw	Kilowatt
m ³ /hr	Meter cube per hour
μ	Micron