OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

NFD SYSTEM

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

	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR NFD SYSTEM	PROTOCOL No.:
PHARMA DEVILS		

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1.0 PROTOCOL PRE – APPROVAL:

INITIATED 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)			

	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR NFD SYSTEM	PROTOCOL No.:
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2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of NFD System and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Operational qualification protocol cum report is limited to qualification of NFD (Make: A. S. Automations) to be installed in the Tablet inspection.
- This Protocol will define the methods and documentation used to perform OQ activity the Blister-Pack Inspection System for OQ. Successful completion of this Protocol will verify that NFD System meet all acceptance criteria and ready for Performance Qualification.

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	• Initiation, Authorization, Review and Compilation of the OQ Protocol cum Report. • Co-ordination with Production and Engineering to carryout OQ. • Monitoring of Operational Qualification Activity.
Production	• Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol after Execution.
Engineering	• Review of Protocol cum Report. • Co-ordination, Execution and technical support in NFD System OQ Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Review of Qualification Protocol after Execution

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:

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By Sign & Date	Verified By Sign & Date
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	SOP for operating & Cleaning of NFD System				

8.0 CRITICAL VARIABLES TO BE MET:

8.1 VERIFICATION OF HMI PARAMETERS ACCESS:

Operate the NFD System as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

Function	Operation	Acceptance criteria	Observation (Ok/Not Ok)
1. MAIN SCREEN			
Main Screen	Production counters	Displays : GOOD: Number of Good Strips scanned by NFD PARTIAL: Number of partial strips Scanned by NFD EMPTY: Number of Empty Strips Scanned by NFD Total: sum of above counters	
	Production counter reset	Press the on the production counter table. Small window will pop up. Press YES to reset button to reset all counters.	
	Product name	Displays: Current Loaded Recipe Name.	
	Logged in	Displays Current Logged In User Remains Blank when all users logged out.	
	Log in	Press this Button to login as a user.	
	Logout	Press this button to Logout from current logged in user.	
	Speed	Displays: Speed of machine in terms of cuts per Minutes	
	Encoder	Displays: Encoder position in terms of 0°-1024°	
	Speed	Displays: Speed of machine in terms of cuts per Minutes	
	Encoder	Displays: Encoder position in terms of 0°-1024°	
	Name of selected NFD type	NFD- Universal Sensing NFD- IR Sensing.	
2. Screen- SET NFD			
SET NFD mode	1.NFD type	**UNIVERSAL SENSING:** NFD will detect tablets by Mechanical Sensors. **IR Sensing:** NFD will detect tablets by IR channel sensing module	
	2.NFD mode	**NFD AUTO** : NFD will work as per setting **Manual Accept Mode**: NFD bypass Mode **Manual Reject Mode**: NFD bypass mode	
	3.Reject Buzzer	**OFF** : Reject buzzer off **ON** : Reject Buzzer ON for Empty detection	
Parameter	Strip length	Enter Strip length in mm	
	Toes	No of Toes on cam disc.	
	Tracks	No of strips produced in one cutting operation.	
	Sensor count	No of tablets to be sense by sensor in on row	
	Column/Track	No of sensors used in one strip.	
	NFD reject	No of strips from sensing roller to flapper. (Will Load	

Function	Operation	Acceptance criteria	Observation (Ok/Not Ok)
	length	automatically when you press SET HOME button)	
Flapper Select	FLAPPER 1	Select **STRIP 1 - STRIP 7** for which flapper 1 will operate. When unused- select **NOT USED**	
	FLAPPER 2	Select **STRIP 1 - STRIP 7** for which flapper 2 will operate. When unused- select **NOT USED**	
	FLAPPER 3	Select **STRIP 1 – STRIP 7** for which flapper 3 will operate. When unused- select **NOT USED**	
	FLAPPER 4	Select **STRIP 1 - STRIP 7** for which flapper 4 will operate. When unused- select **NOT USED**	
	FLAPPER 5	Select **STRIP 1 - STRIP 7** for which flapper 5 will operate. When unused- select **NOT USED**	
	FLAPPER 6	Select **STRIP 1 - STRIP 7** for which flapper 6 will operate. When unused- select **NOT USED**	
	FLAPPER 7	Select **STRIP 1 - STRIP 7** for which flapper 7 will operate. When unused- select **NOT USED**	
Clock & Flap	Set home	Press SET HOME Button **When** 1. New Product change over. **How** 2. Inch machine slowly till cutter moving end cuts the strip. (Cutter should be in close position) at this point Press SET HOME. **TO** 1. Load Clock cam, Flap cam, tablet Hold cam automatically. Clock cam: Defines the position when sensing rollers are in between two strips. Flap Cam: Defines the position where flapper will operate Tablet Hold cam: Defines the position where tablets hold mechanism operate.	
	Adjust	Press Adjust button to open settings below Adjust flap operating position: shift flap position up and down in terms of cavity. Use Shift Up and Shift down button Adjust Tablet Hold position: Shift tablet hold position up and down. Use Shift Up and Shift down button	
	View (tablet cam)	Press This button to view Tablet Cam Position. Tablet Cam: Defines the position window of every cavity where sensing will be done. Sensors will check the presence and absence of tablets in this window. Cavity 1- Cavity 7 Start- Staring of sensing cam. End: end of sensing cam.	
Extra	**DRY PRINT REJECT:**		

Function	Operation	Acceptance criteria	Observation (Ok/Not Ok)
Rejection	Dry Print strips generated regularly when m/c stop for certain time periods. To reject these strips is the main purpose of this provision. This provision is interlinked to tablet hold so rejected strips will be completely empty.		
	Dry print rejection	ON: Print rejection provision ON OFF: Print Rejection Provision OFF	
	Dry print reject length	No of strips from Printing station to Feeding. (Will Load automatically when you press SET HOME button)	
	Dry print reject count	No of strips to be rejected for print rejection	
	Machine stop time (in seconds)	Machine stop time (Sec) to activate this Provision	
	TABLET REJECTION Tablets will burn when machine stop for certain time periods. To reject those strips having burnt tablets is the main purpose of this provision.		
	Burn tablet rejection	ON: Sealing rejection provision ON OFF: Sealing Rejection Provision OFF	
	Burn tablet reject length	No of strips from Sealing station to flapper. (Will Load automatically when you press SET HOME button)	
	Burn tablet reject count	No of strips to be rejected for Sealing rejection	
	Machine Stop Time (In Seconds)	Machine stop time (Sec) to activate this Provision	
RECIPE	DOWNLOAD RECEIPE Download selected Recipe to PLC.	1. Press this button to **Open Down load recipe Screen** 2. Select Product from the earlier saved List. 3.Press **LOAD button** to download the Recipe in PLC	
	Create new recipe **Create new recipe & save.**	1. Press this button to open Create New recipe Screen**.** 2. Type Product Name In Recipe name text box 3. Press SAVE button to save current loaded NFD parameters under entered product name.	
	DELETE RECEIPE Delete saved recipes	1. Press this button to open delete recipe Screen**.** 2. select recipe name to be delete 3. Press DELETE button to Delete selected recipe from memory.	
3. MONITOR			
MONITOR	Strip Status Monitor	Red Indication: stands for empty cavity Green Indication: stands for Presence of tablet/capsule in a cavity. STRIP1- STRIP 7: Indicates the strip number read	

Function	Operation	Acceptance criteria	Observation (Ok/Not Ok)
		from machine wall side.	
4 ADMIN			
ADMIN SETTING	STAND BY OUTPUT SELECTION 1. Default assigned PLC Outputs for Rejection solenoid are from Y0- Y5 & Tablet hold solenoid. 2.In case of any failure in above outputs Stand by outputs Y20-Y27 can be assign for rejection solenoid.	Following outputs can be assign to Rejection solenoid TR1 to TR7 Flapper 1 S.V. for Output Y20: ON/OFF Flapper 2 S.V. for Output Y21: ON/OFF Flapper 3 S.V. for Output Y22: ON/OFF Flapper 4 S.V. for Output Y23: ON/OFF Flapper 5 S.V. for Output Y24: ON/OFF Flapper 6 S.V. for Output Y25: ON/OFF Flapper 7 S.V. for Output Y26: ON/OFF Tablet Hold S.V. for Output Y27:ON/OFF	
	STAND BY OUTPUT SELECTION 1.Default assigned PLC Outputs for buzzer, NFD power relay, IR NFD Power relay and M/c stop relay are from Y10- Y14 2.In case of any failure in above outputs Stand by outputs Y30-Y34 can be assigned for above outputs.	Following outputs can be assigned as follows ➤ Buzzer for Output Y30: ON/OFF Inductive NFD power relay for Output Y31: ON/OFF. IR NFD power relay for Output Y32: ON/OFF ➤ M/c stop relay for Output Y34:ON/OFF	
	SECURITY LEVEL SETTING Press **EDIT** Button to Open Security level setting screen		
	ADD	To Add New User 1. Enter user Name 2. Enter password 3. Enter Description (optional) 4. Press NEXT button 5. Select Security Group/Level 6. Press Finish.	
	Edit	To Edit Current User setting 1. Select user to be edit	

Function	Operation	Acceptance criteria	Observation (Ok/Not Ok)
		2. Then Press EDIT button 3. Change User Name, and password, Description. 4. Press NEXT button 5. Select Security Group/Level 6. Press Finish.	
	Time date setting	To change/edit press EDIT button	
	I/O Details	To View Input Output details of PLC Press VIEW Button For PLC input list Press INPUT X0- X47 For PLC output list Press OUTPUT Y0-Y37	
	NFD Cam Setting	NFD cam setting (Clock Flap and Tablet Hold) has two modes AUTO MODE: All cam values will be loaded Automatically when we press Set Home Button. Manual Mode: In manual Mode cam Values will be loaded manually. (Optional)	
4.ALARM			
ALARM	Columns in alarm window	STATE: Status of alarm like Active/Acknowledged/Normal/Inactive ACTIVE TIME: Time at which alarm raised TEXT: Name of an alarm.	
	ACK selected	Press to Acknowledge Selected alarm only.	
	ACK all	Press to Acknowledge all alarm.	
	Clear	Press To Clear all alarms having NORMAL status.	
	Alarm indication lamp	When Alarm generated by the system 1. Indication lamp blinks red on the screen 2. Indication lamp goes green and blinks when it is acknowledged. 3. Disappear when all alarms are cleared.	

Checked By
Sign & Date:

Verified By
Sign & Date:

8.2 CHALLENGE TEST FOR NFD SYSTEM:

Test	Procedure	Acceptance Criteria	Observation (Complies/not complies)
Verification of sensing roller assembly Unit	➤ Set sensing roller assembly in front of each cavity. ➤ Set the Product check sensor below the SS strip of sensing roller assembly ➤ Tighten the locknut of sensing roller assembly. ➤ Set Support rings on the knurling part of each cavity. ➤ Fix and Tighten locking plate for sensing roller bracket and support roller bkt. ➤ Take the strips with filled cavity in front of sensing roller assembly. Set the deflection of SS strip it should be around 8-10mm from sensor. ➤ Take the strips with empty cavity in front of sensing roller assembly. Set the deflection of SS strip it should not deflect.	➤ For filled cavity sensing roller assembly's SS strip should deflect 8-10mm from the sensor face. Sensor's Orange light should be OFF. ➤ For Empty Cavity sensing roller assembly's SS strip should not deflect from the sensor face. Sensor's Orange Light should be ON.	
Verification of Rejection flapper	➤ Take the strips below cutter to create reference. ➤ Assign and Set the rejection flapper for each strip Start.	Each individual strip should be guided properly to fall either in Reject side or Accept side	
Testing of empty pocket detection and rejection	➤ Ensure that NFD switch on control panel is in AUTO mode. ➤ Start Strip Packing Machine with tablets. ➤ Stop any one tablet from track number 1. (Nearest to the strip packing machine). ➤ Repeat step no. 3 till you have succeeded in stopping first tablet in a row in a strip. ➤ Repeat step no. 3 till you have succeeded in stopping last tablet in a row in a strip.	All strips with empty pocket should get rejected.	
Testing of Tablet Hold provision	➤ Run strip packing machine with tablets/ capsules (as per the product) ➤ Turn on Tablet Hold switch (Hardware toggle s/w) on control panel ➤ After passing two three strips turn off the switch.	➤ When switch is ON, tablets flowing from feeding channel should get hold/stop exactly at strip is end. ➤ When switch is turned from ON to OFF, tablets should start to	

Test	Procedure	Acceptance Criteria	Observation (Complies/not complies)
		fill the cavities exactly from the beginning of strips.	
Testing of Dry Print rejection provision	➤ Ensure that Dry Print rejection facility is on. ➤ Run strip packing machine with tablets/ capsules (as per the product). ➤ Stop the machine sufficiently long (machine stop time entered in parameter) till ink on transfer roller\stereos of printing unit dries. ➤ Make a horizontal mark on the plain foil near the printing position to mark start of dried ink patch. ➤ Start strip packing machine and run it without producing even a single empty pocket.	The strips with and after the mark (No's as specified in Reject Count) should get rejected	
Testing of Burn Tablet rejection provision	➤ Ensure that Burn tablet rejection facility is on. ➤ Run strip packing machine with tablets/ capsules (as per the product) ➤ Stop the machine for little longer than machine stop time entered in parameter to simulate burning of tablets in between rollers. ➤ 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. ➤ Start strip packing machine and run it without producing even a single empty pocket.	The strips with and after the mark (No's as specified in Reject Count) should get rejected.	
Testing of Low Air Pressure Interlock	➤ Ensure that the pressure switch is set to 3 bar. ➤ Decrease the pressure below set point.	Strip packing machine should stop with buzzer indication. Low air Pressure Alarm should be displayed in ALARM screen of HMI.	
Testing of NFD Bypass Interlock	➤ Select the NFD mode Manual Accept ➤ Select NFD mode Manual Reject	➤ In Manual Accept Mode M/c should stop with buzzer Indication and in Manual Reject Mode M/c should not stop only buzzer indication	

Test	Procedure	Acceptance Criteria	Observation (Complies/not complies)
		➢ In manual accept mode or manual reject mode alarm should be displayed in ALARM screen of HMI.	

Checked By
Sign & Date:

Verified By
Sign & Date:

8.3   POWER FAILURE VERIFICATION:

Item	Acceptance Criteria	Observation (Ok/Not Ok)	Observed By Sign & Date
Main Power shut down	Equipment stops in safe and secure condition		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

8.4   VERIFICATION OF USER LEVELS CONTROLS:-

Operation Level	Acceptance Criteria	Observation (Ok/Not Ok)
Operator Level	Operator level should have access to process selection, process start & stop & visualization.	
Supervisory Level	Supervisory level should have access to operator level all menu and in addition to that, should have excess to set the process parameter, recipe preparation & recipe upload	
Administrative Level	Administrative should have access to supervisory level all menus and in addition to that, should have excess to change the password.	

Checked By
Sign & Date:

Verified By
Sign & Date:

Inference:

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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, Plant and Equipment for Pharmaceutical Products."

- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing   Practices and Inspection.

10.0   DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

11.0   DEVIATION FROM PREDEFINED 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

	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR NFD SYSTEM	PROTOCOL No.:
PHARMA DEVILS		

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:

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HEAD (QUALITY ASSURANCE)			