PHARMA DEVILS
PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Non Fill Detection System	PROTOCOL No.:.........................
FUNCTIONAL AREA: Production	Page No.: 1 of 9

USER REQUIREMENTS SPECIFICATION

FOR

[NON FILL DETECTION (NFD) SYSTEM]

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1.0 General Information

Name of Equipment/Instrument/System/Model/Make	Non Fill Detection system/GMP Model/AS Automation.
Brief description about the configuration of equipment/ instrument/system	- NFD systems are used to detect empty pockets while stripping. - To detect empty pocket & reject online. - Proposed NFD system shall be compatible with Satellite strip pack machine. - Provision for six track rejection arrangement as per strip size. - Provision for collection of rejected strips shall be provided. - Rejection system of universal type with stand mounting arrangement shall be provided. - Control panel shall contain ON/OFF switch. - Mounting arrangement for encoder shall be provided. - Provision shall be provided in software for good/bad strips counting, No.of rows/track setting, - Provision shall be provided for sealing rejection, dry ink rejection through NFD logic. - NFD system & its accessories shall have provision of easy dismantling & cleaning for different pack sizes. - Also provision shall be provided to stop & operate the machine without any setting disturbance. - Design of the system shall facilitate easy cleaning & maintenance. - PLC-MMI based version. - Proposed NFD system shall be flexible in system software for different change parts. - Design of the system shall conforms to cGMP norms. - Number of tracks configurable upto 12 tracks. - Minimum sensing of tablet/capsule –2.8 mm in thickness.
Quantity required	01 No.
Purpose of the equipment (Specific application)	To detect empty pocket and reject them online during stripping.

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2.0 User Requirements

Sr. No	Parameters	Requirements Specification
2.1	**Material of construction of components/ accessories**	All product contact parts in SS 304. All other non-contact parts in SS 304.
2.2	**Specification of equipment/instrument/ system at the installation site** ➢ Width ➢ Length ➢ Height	Vendor has to confirm the Dimensions.
2.3	**Description of Accessories** ➢ List of Accessories ➢ Dimensions	NA NA
2.4	**Location Suitability** ➢ Installation Space ➢ Operational Space	Length (L) X Width (W) X Height (H) = 5.00 m X 5.31 m X 4.70 m
2.5	**Details of utilities required** ➢ Air, Water, Nitrogen, Hydrogen etc. ➢ Compressed air, steam ➢ Electrical supply	NA Compressed air 3Phase/415V/50Hz
	➢ Spike guards ➢ UPS back up system ➢ Air conditioning / HVAC ➢ Air grade of specific class	NA Yes HVAC Grade D
2.6	**Environmental condition at installation site** ➢ Temperature ➢ Humidity ➢ LUX level at working place ➢ Noise level in decibels	25°c±2°c 40 ±10% NLT 300 LUX NMT 80 DB

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Sr. No	Parameters	Requirements Specification
2.7	**Level of Automation** ➢ Fully Automatic (PLC based etc.) ➢ Semi Automatic ➢ Manual	 PLC based NA NA
2.8	**Capacity and use** ➢ Max. Operating capacity	 Vendor has to conform the maximum operating capacity. Typically 55 cuts/Minutes.
2.9	**Safety** ➢ Personnel safety ➢ Environmental hazard if any	 No person shall be allowed to work on the machine unless the person has been fully trained. NA
2.10	**Speed** ➢ RPM ➢ Operational speed	 NA Typically 55 cuts / Minutes.
2.11	**Nature of products to be handled**	Materials used is non-corrosive, may be weak acidic / alkaline in nature.
2.12	**Cleaning process parameters to be controlled** ➢ Clean in Place ➢ Manual Cleaning ➢ Water, Detergents, Solvents ➢ Cleaning procedure	 NA All contact parts shall be easily accessible for washing. Manual cleaning using lint free cloth. Cleaning procedure shall be provided. Wing nuts shall be provided for easy dismantling & assembling.
2.13	**Critical process parameters to be controlled** ➢ Critical process parameters ➢ Control procedure	 All parameters shall be measured, & monitored by PLC. Level of password with authorization.

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Sr. No	Parameters	Requirements Specification
2.14	**Power failure and recovery** ➢ Probability ➢ Recovery procedure	In the event of power failure the system shall protect the personnel, equipment & product. The equipment shall not restart when electricity restored
2.15	**Emergency stop** ➢ Provision for emergency stop	NA
2.16	**Alarm warning** ➢ Indication of abnormality in operation	All the required indications shall be incorporated in PLC.
2.17	**Data security** ➢ Data storage ➢ Data integrity ➢ Data retrieval	NA NA NA
2.18	**Constraints** ➢ Timelines ➢ Delivery	To be delivered at the following site of ………, within 4 to 6 weeks from the date of approved Purchase Order. ………………..
2.19	**Maintenance** ➢ Procedure ➢ Frequency	Vendor has to provide the procedure for maintenance. Vendor has to provide the procedure for maintenance.
2.20	**Computer Configuration** ➢ Details of configuration through computer software	As per vendor recommendations.
2.21	**Computer Hardware & Software Requirement** ➢ Hard disk storage capacity ➢ Compatible software with specific version ➢ 21 CFR part 11 compliant software	As per vendor recommendations. As per vendor recommendations. NA

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Sr. No	Parameters	Requirements Specification
2.22	**User License Requirement** ➢ Availability of sufficient licenses for used dept.	Sufficient licenses shall be available with user dept**.**
2.23	**Commissioning and Documentation** ➢ Availability of the Engineer/s at the time of commissioning ➢ Availability of IQ, OQ, PQ protocols at the time of commissioning	➢ DQ/IQ/OQ to be completed by the supplier (as per …… Protocol) along with ….. representatives. ➢ Test certificate for major bought outs. ➢ Factory – In house test certificate. ➢ Instruction, operation and maintenance manual. ➢ As built drawings. ➢ Equipment electrical drawings. ➢ Ledder logic. ➢ Mechanical drawing. ➢ Electrical wiring diagram. ➢ P & I Diagram. All the MOC/test and calibration certificates shall be collected from vendor and it shall be traceable to National Standards.
3.0	**Training** ➢ Consent for training as and when required to user dept.	Training shall be given by the vendor.
4.0	**Reference documents** ➢ Operating manual ➢ Technical manual ➢ Trouble shooting manual ➢ Test certificates ➢ Calibration certificates	Supplier shall provide all the reference documents along with list of respective change parts & spares to be specified.

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5.0 Abbreviations

Acronym	Definition
IQ	Installation qualification
OQ	Operational qualification
DQ	Design qualification
HVAC	Heating Ventilation & Air Conditioning
RH	Relative Humidity
DB	Descibals

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This document has been prepared by User department, reviewed by Engineering and safety, approved by Quality Assurance, Unit Head and authorized by Functional Head. This document shall be sent to supplier / vendor for his acceptance.

APPROVALS

PREPARED BY: _____   DATE: _____
                         (USER DEPARTMENT)

REVIEWED BY: _____   DATE: _____
                         (ENGINEERING / SAFETY)

APPROVED BY: _____   DATE: _____
                         (QUALITY ASSURANCE)

APPROVED BY: _____   DATE: _____
                         (UNIT HEAD)

AUTHORIZED BY: _____   DATE: _____
                         (FUNCTIONAL HEAD {CORPORATE})

ACCEPTED BY: _____   DATE: _____
                         (NAME, STAMP & SIGNATURE OF
                          SUPPLIER / VENDOR)