



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

User Requirement Specification for Fix Conveyor 2000 MM Length

**USER REQUIREMENTS SPECIFICATION
FOR
FIX CONVEYOR 2000 MM LENGTH**

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1.0 Introduction:

This document prepared to provide user requirement specification for equipment **Fix Conveyor 2000mm Length**. This document covers the technical specification for equipment **Fix Conveyor 2000 mm Length**.

This is important for equipment that is part of integrated process or line and will help supplier to understand the user's requirements.

2.0 Overview:

2.1 Intended use

2.1.1 For pharmaceutical products

2.2 Production Capacity

2.2.1 The capacity of the Fix Conveyor 2000 mm Length.

2.3 Space Availability

2.3.1 Allocated floor space for the machine is 3800 mm X 4590 mm and vertical clearance is 3000 mm.

2.4 Accuracy of instrumentation desired:

2.4.1 Not Applicable

2.5 Cleaning requirement:

2.5.1 Easy to clean (clean in place)

2.6 Equipment specific requirement

2.6.1 It should be designed to meet latest cGMP standards & should have low maintenance cost.

2.6.2 Equipment shall have

- Fix over pipe.
- Conveyor belt.
- A. C. Frequency Drive.
- Control panel.

2.6.3 SS304- conveyor guide and conveyor belt made of Delrin.

2.6.4 - Safety features: NA

2.6.5 Spare parts required: NA



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3.0 Operational Requirements:

3.1 Functional Requirements

3.1.1 Operation

3.1.1.1 All control will be positioned where the operator has a full view of the system/equipment.

3.1.1.2 Operation shall be safe from an operator and environment standpoint.

3.1.2 Control System Requirements

3.1.2.1 Controlling system of Fix Conveyor should be manual.

3.1.2.2 There should be an "ON", "OFF" switch and speed regulator port. Speed control through ACVFD.

3.1.2.3 All devices and wiring which are located inside of operation panel will be suitably protected from physical damage.

3.1.3 Alarms and Warnings

3.1.3.1 NA

3.1.4 Power failure / Recovery

3.1.4.1 In the event of a power failure, the system shall protect in the following priority:

Personnel
Equipment
Product

3.1.4.2 In the event of a power failure, the system shall stop automatically and will require operator intervention to re-start.

3.1.5 Safety Requirements

3.1.5.1 Grounding: proper earthing should be provided.

3.2 Environment

3.2.1 The Fix Conveyor 2000 mm Length will be installed in an environment with a temperature range of NMT 25°C & % RH of NMT 60%.

3.3 Other requirements

3.3.1 M. O.C. SS304 conveyor guide and conveyor belt made of Delrin.

4.0 Compatibility and Support:

4.1 Utilities

4.1.1 The supplier shall indicate the requirement of utilities to be provided by the user while submitting the design specification.

4.1.2 Base Utilities Worksheet:

Electricity: Single phase, 220V AC, 50 Hz, 0.5HP

4.1.3 Other utility requirements shall be discussed as needed.

4.2 Availability

4.2.1 **Fix Conveyor 2000 mm Length** is intended to be operated: Regularly 3 shifts.

4.3 Procedural document requirements

4.3.1 Supplier has to provide,

- Detailed functional specification
- Design Qualification, Installation Qualification, Operational Qualification
- Material Test Certificate for Contact parts
- Surface Finish Test Report



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- Installation, operation & maintenance Manual with spare List
- Warranty Certificate of machine ,
- Certificates & Manuals of brought out items including calibration

4.4 Process requirements:

For Pharmaceutical products

4.5 Data and Security

4.5.1 Controls provided with Data Collection systems shall be required to meet **21 CFR Part 11 compliance**

-Audit trail facility is required.

4.5.2 User interface access levels/level of automation

NA

4.5.3 Language requirements

English

4.5.4 Display Requirements

Measurement to be used- Metric (SI)

4.5.5 Interface with other equipment

NA

4.5.6 Data collection (archiving & reporting requirements)

NA

5.0 Constraints:

5.1 Milestones and Timelines

5.1.1 The Supplier shall notify the User three weeks in advance of the start of Factory acceptance test.

The Factory Acceptance Test Specification shall be submitted to the User for review and approval prior to execution. A minimum of two weeks shall be allowed for the User to review and to comment and/or approve the Factory Acceptance Test Specification.

The User shall notify the Supplier of the length of runs required, special materials required, and any other unique test requirements two weeks in advance of the start of testing.

5.2 Equipment Constraints

5.2.1 Noise Level Constraints:

NA

5.2.2 Preferred Vendor List:

NA

5.3 Labelling

5.3.1 All equipment and control wiring shall be labeled and identified.

5.4 Testing

5.4.1 In order to verify system performance, the User shall witness the execution of the Factory Acceptance Test procedures.

5.5 Delivery

5.5.1 All final documents shall be shipped with transmittals that identify them as contractually required documents. All final documents and drawings shall reflect "as-built" condition

5.5.2 All documents shall be in the language of the English and supplied with hard copies and electronic versions supplied in the format identified for each document.



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5.6 Support

5.6.1 Start-up Support:

- Training

5.6.2 Post Start-up Support:

Technical Support:

- Telephone
- Replacement Parts Availability List

User Site Support

- Preventative Maintenance (list maintenance contracts available)
- System Improvements (supplier shall notify user of any improvements available on a regular basis)

6.0 Abbreviation:

Acronym	Definition
°C	Degrees Celsius
%	Percentage
URS	User Requirement Specification

7.0 References:

Nil

8.0 Attachments:

Nil

9.0 Approvals:

	Name	Designation	Sign	Date
Prepared by				
Checked by				
Approved by				
Authorized by				