



**PHARMA DEVILS**  
**QUALITY ASSURANCE DEPARTMENT**

**User Requirement Specification for Automatic Visual Vial Inspection Machine**

**USER REQUIREMENTS SPECIFICATION  
FOR  
AUTOMATIC VISUAL VIAL INSPECTION  
MACHINE**

**Table of contents**

<b>1.0</b>	<b>Introduction</b>	<b>3</b>	
<b>2.0</b>	<b>Overview</b>	<b>3</b>	
<b>3.0</b>	<b>Operational Requirements</b>	<b>3-5</b>	
	<b>3.1</b>	<b>Functional Requirements</b>	<b>3</b>
	<b>3.2</b>	<b>Environment</b>	<b>4</b>
	<b>3.3</b>	<b>Other requirements</b>	<b>4-5</b>
<b>4.0</b>	<b>Compatibility and support</b>	<b>5-6</b>	
	<b>4.1</b>	<b>Utilities</b>	<b>5</b>
	<b>4.2</b>	<b>Availability</b>	<b>5</b>
	<b>4.3</b>	<b>Procedural documents requirements</b>	<b>5</b>
	<b>4.4</b>	<b>Process requirements</b>	<b>5</b>
	<b>4.5</b>	<b>Data and security</b>	<b>5-6</b>
<b>5.0</b>	<b>Constraints</b>	<b>6-7</b>	



# PHARMA DEVILS

## QUALITY ASSURANCE DEPARTMENT

### User Requirement Specification for Automatic Visual Vial Inspection Machine

	5.1	Milestone and Timelines	6
	5.2	Equipment Constraint	6
	5.3	Labelling	6
	5.4	Testing	6
	5.5	Delivery	6-7
	5.6	Support	7
6.0	Abbreviations		7
7.0	References		7
8.0	Attachments		7
9.0	Approval		8

#### 1.0 Introduction:

This document prepared to provide user requirement specification for equipment. This document covers the technical specification for equipment **Automatic Visual Vial Inspection Machine**. This document covers the technical specification for equipment Automatic Visual Vial Inspection Machine.

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 Multimill is to be 25-300 Kg/Hrs (through 1 mm sieve approx..)

##### 2.3 Space Availability

2.3.1 Allocated floor space for the machine is 870 mm X 900 mm and vertical clearance is 3800 mm

##### 2.4 Accuracy of instrumentation desired:

2.4.1 Not Applicable

##### 2.5 Cleaning requirement:

2.5.1 Easy to clean (easily accessible for cleaning & 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

- Control Panel.
- Machine Frame structure
- Chain Roller Turn table plate

2.6.3 All the contacts parts made up of SS304 with mirror polish.

2.6.4 Multimill should be provided with 3HP

2.6.5 Safety features:

NA



# PHARMA DEVILS

## QUALITY ASSURANCE DEPARTMENT

### User Requirement Specification for Automatic Visual Vial Inspection Machine

- 2.6.6 Spare parts required:  
NA

### 3.0 Operational Requirements:

#### 3.1 Functional Requirements

##### 3.1.1 Operation

- 3.1.1.1 The rollers move round which in turns the vials round so that the operator can see from every side
- 3.1.1.2 Machine should be suitable for four operators, two operators from each side

##### 3.1.2 Control System Requirements

- 3.1.2.1 Operator message display terminals are preferred with warnings lamps.
- 3.1.2.2 There should be an “ON”, “OFF”, “INCH” switch. And speed regulator. Indicator lamp for clutch, selector switch for light ON/OFF.
- 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. Micro switch & emergency stop

#### 3.2 Environment

- 3.2.1 Automatic Visual Vial Inspection Machine 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.- Non contacts parts-MS clad with SS304 mirror polish.

### 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: 3 phase, 415V AC $\pm$ 6%, 50Hz +neutral (4 wire)
- 4.1.3 Other utility requirements shall be discussed as needed.

#### 4.2 Availability

- 4.2.1 Automatic Visual Vial Inspection Machine is intended to be operated: Regularly.

#### 4.3 Procedural document requirements

- 4.3.1 Supplier has to provide,



# PHARMA DEVILS

## QUALITY ASSURANCE DEPARTMENT

### User Requirement Specification for Automatic Visual Vial Inspection Machine

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

NA

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



# PHARMA DEVILS

## QUALITY ASSURANCE DEPARTMENT

### User Requirement Specification for Automatic Visual Vial Inspection Machine

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 in the language of the English and supplied with hard copies and electronic versions supplied in the format identified for each document.

#### 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
db	Decibel
%	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				



# PHARMA DEVILS

## QUALITY ASSURANCE DEPARTMENT

### User Requirement Specification for Automatic Visual Vial Inspection Machine