# USER REQUIREMENT SPECIFICATION

**NAME OF THE ITEM: TABLET INSPECTION MACHINE**

**FUNCTIONAL AREA: PRODUCTION**

**PROTOCOL No. :……**

| USER REQUIREMENT SPECIFICATION | |
|---|---|
| **NAME OF ITEM:** Tablet Inspection Machine | **PROTOCOL No.....** |
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## 1.0 URS APPROVAL:

**Protocol Prepared By:**

| Functional area | Name | Signature | Date |
|---|---|---|---|
| Production | | | |

**URS Reviewed By:**

| Functional area | Name | Signature | Date |
|---|---|---|---|
| Production | | | |
| Quality Assurance | | | |
| Engineering | | | |

**URS Approved By:**

| Functional area | Name | Signature | Date |
|---|---|---|---|
| Head Engineering | | | |
| Head Manufacturing | | | |
| Head Quality | | | |

**2.0 Objective:**

The purpose of this document is to ensure that all the critical aspects of the Equipment, cGMP & Safety features have been considered in designing the equipment/instrument and is properly documented.

**3.0 Responsibilities:**

In accordance with the document, following functions shall be responsible for initiation and finalization of Equipment user requirement specification. When the work is carried by contract/consulting staff, all the work is to be performed under the oversight of ……..

**3.1 Preparation of Document**

- User department to prepare the URS
- Ensures that the document is in compliance with current policies and procedures of cGMP regulations.
- Ensures that the content is sufficient, clearly defined, technically sound and accurate.
- It is a Guidance document to prepare the URS.

**3.2 Review of Document**

- To be reviewed by Head of the user department and functional department ( Engineering & Quality assurance)

**3.3 Approval of Document**

- Approval of document by Head Manufacturing/Head Engineering/Head Quality.

**4.0 Equipment Description & Identification:**

**4.1 Scope:**

This document covers all aspects of Users requirements for the Equipment along with all Attachment, Spare Parts, Change Parts and Accessories to be used in ……

Scope incorporates understanding and documentation of critical requirements such as system requirements, cGMP requirements, safety requirements, documentation requirements and operational requirements.

**4.2 Purpose:**

Purpose of equipment is used in production area for the inspection of tablets and capsules.

**5.0 USER REQUIREMENTS**

**5.1 System Requirements:**

PHARMA DEVILS

PRODUCTION DEPARTMENT

**USER REQUIREMENT SPECIFICATION**

| | |
|---|---|
| **NAME OF ITEM:** Tablet Inspection Machine | **PROTOCOL No.....** |
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| S.No. | SYSTEM COMPONENTS | SYSTEM REQUIREMENTS |
|---|---|---|
| 1. | Identification (In case of Equipment /Instrument) | Details of Make, Name, Serial. No., Capacity, Model and Year of manufacture should be available |
| 2. | Model/Type | As per current cGMP requirements. |
| 3. | Capacity | 0.25 HP / 1440 RPM / 3 Ph. 145 mm width, 540 mm (W) X 1955 mm (L) X 1270 mm (H). |
| 4. | Potential Suppliers | 1. Pam Packages Pvt. Ltd.<br>2. ACME Pharma or Rangnathan |
| 5. | Contact parts (In case of Equipment) | SS316 L with Mirror finish. |
| 6. | Non contact parts (In case of Equipment) | SS304 with matt finish. |
| 7. | Non metallic contact parts (In case of Equipment /Instrument) | 1. Any material with food grade quality having no Potential impact on the products.<br>2. Durable.<br>3. Must be easily cleanable. |
| 8. | Motor & Electrical installations (In case of Equipment /Instrument) | As per machine requirement |
| 9. | Machine assemblies (In case of Equipment /Instrument) | Must be covered with SS 304 with matt finish. |
| 10. | Machine adjustments (In case of Equipment /Instrument) | Setting with Zero clearance with good accuracy. |
| 11. | Packaging & Transport | Should be packed and transported in such a way to avoid any damage during transportation. |
| 12. | No. of requirements | 02 |
| 13. | Requirements for any power failure backup's (In case of Equipment /Instrument) | To be backed up by installed in-house DG set. |

### 5.2 Technical Description

| S.No. | Specification | SYSTEM REQUIREMENTS |
|---|---|---|
| 1. | Vibration mechanism with Hopper | YES |
| 2. | Foot switch | YES |
| 3. | Unit is mounted on Castor Wheel. | YES |
| 4. | Light Stand | YES |
| 5. | Control Panel | YES |

## 6.0 COMPLEMENTARY ASPECTS:

### 6.1 Training

| S.No. | Specification | SYSTEM REQUIREMENTS |
|---|---|---|
| 6.1.1 | The vendor Shall supply all available information for the adequate exploitation of equipment. For the Compliance of this purpose at the Job site and/ or at the Vendors Shop. Vendor's technical staff shall train customer's personnel. The scope of the Training will be agreed during the contract signature. | YES |
| 6.1.2 | The supplier is to include the personnel training activities. The supplier is to specify the foreseen time for:<br>• Operator/Supervisor training<br>• Manager Training<br>• Electrical maintenance training<br>• Mechanical Maintenance training | YES |
| 6.1.3 | The supplier is to specify the personnel background needed for each of the operators maintenance. | YES |

### 6.2 Pre Delivery Qualifications (FAT)

| S.No. | Specification | SYSTEM REQUIREMENTS |
|---|---|---|
| 6.2.1 | The System or its parts as provided for in the scope of supply shall be pre-installed at the vendors shop prior to delivery to customer site. Installation will be completed and documented including mechanical parts as well as electrical connections of all parts to facilitate taking over tests at Vendors shop prior to delivery. FAT checklist should be send by vendor to the company before FAT Scheduling and reviewed. | YES |

### 6.3 Supplier Technical Documentation Requirements:

| S.No. | COMPONENTS | REQUIREMENTS |
|---|---|---|
| 6.3.1 | **Drawings**<br>• Equipment/Systems electrical drawing.<br>• Point to point wiring diagram | Pre Installation Requirements will be supplied by Vendor |
| 6.3.2 | **LIST.**<br>• Equipment and instrument list with Component description.<br>• Electrical component parts list with Description.<br>• Function check list.<br>• Documentation list.<br>• Spare part list | YES<br>YES<br>YES<br>YES<br>List of spares required for smooth operation will be provided by the Vendor at the time of ordering. |

### 6.4 Technical Manuals

| S.No. | Specification | Requirements |
|---|---|---|
| 6.4.1 | Operating handbook | YES |
| 6.4.2 | Trouble Shooting Guide | YES |
| 6.4.3 | Equipment Description | YES |
| 6.4.4 | Equipment specification | YES |

### 7.0 SAFETY AND ENVIRONMENTAL PROTECTION

| S.No. | Specification | Requirements |
|---|---|---|
| 7.1 | All motors have to be thermally Protected. | YES |
| 7.2 | All the Installation must be in accordance with the cGMP. | YES |
| 7.3 | The cGMP concerning safety must be applied. | YES |

### 8.0 CLEANING MAINTENANCE AND SERVICE

| S.No. | Specification |
|---|---|
| 8.1 | In accordance with cGMP guidelines the units must be easy to clean and where necessary. |
| 8.2 | The Supplier should guarantee that, if required, a service team can be on site within one working day. |

| | |
|---|---|
| 8.3 | The design should be such as to allow mechanical cleaning of the surface and that the cleanliness of the surface can be checked easily. |
| 8.4 | All machine parts, in particular instrumentation, should be constructed so that they can be easily removed and calibrated. |
| 8.5 | All special tools required for running and maintenance should be best. |
| 8.6 | A spare parts delivery guarantee with in time. |

## 9.0 RULES AND REGULATION:

These standards, recommendation and requirements are considered the minimum. Specifications that are more stringent or expansive take the precedence. In case of conflict between published requirements, final determination is the responsibility of the Owners Representative.

## 10. SCOPE OF DELIVERY:

| S.No. | Specification | Requirements |
|---|---|---|
| 10.1 | Units described in the specific system requirements including all necessary controls and instrumentation. | YES |
| 10.2 | The complete mechanical and electrical installation. | YES |
| 10.3 | The Connections to all the necessary utilities, exhaust, and waste lines necessary for its operation. | Yes |
| 10.4 | All piping and cabling of the units itself. | YES |
| 10.5 | Wiring and cable run: all wiring and cable run is part of the supply. …….. will supply the main power switches to be located in correspondence to the electrical and control cabinets delivered by the equipment supplier. | YES |
| 10.6 | All internal contacts of the supplied equipment for the required utilities. | YES |
| 10.7 | Unload on site of the equipment: the supplier is required to define all the necessary handling devices required to the unloading operation. The supplier will inform at least 4 weeks in advance the day of delivery and the list of required handling devices. | YES |
| 10.8 | Assembling operation: the required consumable, the internal transportation, the assembling tools and the required personal are part of the supply. | YES |
| 10.9 | A complete set of commissioning spare parts. | YES |
| 10.10 | All special tools necessary for use and maintenance of the supplied equipment. | YES |
| 10.11 | A complete set of two years spare parts should be listed quoted and offered as option. | YES |
| 10.12 | All test activities as specified in this document. | YES |
| 10.13 | Training in the use and maintenance of the equipment. | YES |

| S.No. | Specification | Requirements |
|---|---|---|
| 10.14 | A complete set of documentation as specified in this document. | YES |

## 11.0 INSTALLATION, COMMISSIONING AND TESTS

### 11.1 General

| S.No. | Specification | Requirements |
|---|---|---|
| 11.1.1 | The Supplier must specify for each piece of equipment the Guaranteed performance and the guaranteed system performance. These values will be tested during the acceptance tests. | YES |
| 11.1.2 | In addition the functionality described in the user requirements and detailed in the system specifications will be tested. | YES |

### 11.2 INSTALLATION , COMMISSION

| S.No. | Specification | Requirements |
|---|---|---|
| 11.2.1 | The commissioning tests will be carried out in accordance with a written test plan developed by the supplier with clearly stated test procedures and acceptance criteria. | YES |
| 11.2.2 | The supplier will approve successfully completed tests and will specify items requiring additional work. Representatives from ……. Will attend and participate in the commissioning tests as required. | YES |
| 11.2.3 | The installation and commissioning of the system will be performed at the ……. Facility by the supplier. | YES |
| 11.2.4 | The commissioning can only start once all the foreseen documents have been delivered by the supplier to …….. | YES |
| 11.2.5 | All equipment should be properly installed, adjusted, leveled, tagged, and connected with utilities. | YES |
| 11.2.6 | Point to point checks on wiring should be performed. | YES |
| 11.2.7 | A equipment (instrument) used for qualification must be listed and approved by ……. | YES |
| 11.2.8 | The last calibration of all this equipment must be less than 6 months | YES |

| S.No. | Specification | Requirements |
|---|---|---|
| | old, and evidenced by certificate. | |
| 11.2.9 | Verification that the interior surfaces of equipment are free of practices and dirt and all points of product contact meet the specified material requirements. | YES |
| 11.2.10 | All the clearances and tolerances specified in the drawing or recommended by component manufacturers are correct. | YES |
| 11.2.11 | On site verification that valves and other equipment with moving parts are in their normal position if in a power down condition and move in the correct direction with the correct speed and precision. | YES |
| 11.2.14 | Verification that all the Input and Output points are connected and labeled according to the documentation and that all the along the input values have been scaled in accordance with the system specification and process requirements. That all equipment components requiring configuration | |
| 11.2.15 | The commissioning should demonstrate that the system supplied by the supplier has been properly installed and that the functions are in accordance with …….. User Requirements specifications, Vendors System specifications Manuals and other Documentation. | YES |

**11.3 Site Acceptance Test (SAT)**

| S.No. | Specification | Requirements |
|---|---|---|
| 11.3.1 | This test will be carried out once the commissioning will be completed. The scope will be to verify the performance and the functionality of the system integrated with the other factory systems. | YES |
| 11.3.2 | The test will be carried out to verify the system response with the expected productivity of the system. | YES |
| 11.3.3 | Details on the test realization will be defined during the project Phase. The supplier is asked to specify the proposed duration for SAT and the standard procedure proposed. | YES |
| 11.3.4 | During SAT the required functionality, performances and system reliability are met. | YES |

| | | |
|---|---|---|
| 11.3.5 | The Functionality described in the User Requirements Specification and in the System Specifications are verified and met. | YES |
| 11..3.6 | All the documentation agreed has been delivered. | YES |

## 12.0 QUALIFICATION / VALIDATION

| S.No. | Specification | Requirements |
|---|---|---|
| 12.1 | The maintenance Qualification is responsibility of the customer. However, the supplier is responsible for delivering the basic documents for maintenance qualification. | YES |
| 12.2 | This includes all side costs such as: calibration measuring equipment and instruments: manpower (IQ and OQ will take place completely on ……...) | YES |
| 12.3 | Time Schedule for IQ/OQ execution will be developed by ……with the supplier. | YES |
| 12.4 | Suppliers personnel used for IQ/OQ must be well trained and experienced. This should be documented. | YES |
| 12.5 | The onsite test run performed by the supplier might become part of the IQ. | YES |
| 12.6 | Main IQ/OQ steps such as calibration must be performed and documented in accordance to a SOP approved by …….. | YES |
| 12.7 | All equipment used for qualification must be listed and approved by ……. The calibration equipment should be well documented. | YES |
| 12.8 | The last Recalibration of all this equipment should be less than 06 month old. Proofed by Certificate. | YES |
| 12.9 | OQ can only start after IQ approved by ……. | YES |
| 12.10 | IQ will be carried out by ……. During Installation phase. IQ will include the tests performed by the supplier. | YES |
| 12.11 | Part of the OQ will be carried out by …….. During commissioning and SAT phase. OQ will include the tests performed by the supplier. | YES |
| 12.12 | After installation of the equipment at customers site. Complementary IQ & OQ tests will be performed by the Customer and may be supervised by a member of Technical staff. | YES |
| 12.13 | Qualification documents (In case of equipments/Instruments) | DQ, IQ, OQ, Test & MOC Certificates |

## 13.0 GAURANTEE/WARRANTEE

| S.No. | Specification | Requirements |
|---|---|---|
| 14.1 | The System must be guaranteed including all the sub- system and components for a period of 12 months from the date of the system acceptance for a 03- shift operation. | YES |
| 14.2 | The servicing companies involved for the Sub- systems maintenance must be declared and the maintenance group organization described. Furthermore, the supplier will be directly responsible of the system assistance and the required operation will be co- ordinate by him. | YES |
| 14.3 | In case of failures, the intervention will be guaranteed by the supplier within a maximum time limit. The supplier is asked to specify the maximum time limit. | YES |
| 14.4 | The supplier is asked to propose as option maintenance and assistance contract after the guarantee expiration. | YES |