USER REQUIREMENTS SPECIFICATION FOR AUTOCLAVE CUM BUNG PROCESSOR

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1.0 Introduction:

This document prepared to provide user requirement specification for equipment. This document covers the technical specification for equipment **Autoclave cum Bung processor.** 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 **Autoclave cum Bung processor** should be 1215 Liters **capacity** approx.

2.3 Space Availability

2.3.1 Allocated floor space for the machine is 1200 mm X 1200 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 (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 –
Chamber Size- 900 (W) X 900 (H) X 1500 (D) mm
Chamber Volume-1215 Liters
Capacity-60,000 Bungs of 20 mm Dia.
Working Pressure- UP TO 2.2 kg/cm^2 (g)
Working Temperature- UP TO 134^{0}C

2.6.3 Chamber material should be SS316L

2.6.4 Spare part:
- NA -

3.0 Operational Requirements:

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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 This machine is fully automatic with PLC

3.1.2.2 There should be an "ON", "OFF", "INCH" switch.

3.1.2.3 Automatic mode

3.1.3 Alarms and Warnings

3.1.3.1 Alarm require

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.

3.1.4.3 Re-start based on last state before loss of power. (System runs through power recovery sequence when operator start signal is given)

3.1.4.4 For automatic batch reporting system, the information shall be retained in the event of power failure.

3.1.5 Safety Requirements

3.1.5.1 MCB will be provided so that when there is an overload in current or any short circuit then MCB trips.

3.1.5.2 All system/equipment guard switches will be undefeatable and will have force disconnection contact arrangement.

3.1.5.3 Grounding: Proper earthing should be provided.

3.1.5.4 Emergency Stop

3.1.5.4.1 The process shall an E-stop mechanism designed to stop all physical movement of the equipment immediately. The E-stop mechanism(s) shall be located in easily accessible areas around the equipment as required by national and local safety standards.

3.2 Environment

3.2.1 Automatic high speed injectable powder filling with rubber stoppering 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 **SS304**.- JACKET, AIR POCKET, SHELL INSULATION, STAND, SKID

3.3.2 **Alu die cost** -Gear Box & Motor

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:
Power estimated 415 V, 50 HZ, 3 Phase
Inductive load estimated 70 KW
Resistance load estimated 7 KW

4.1.3 Other utility requirements shall be discussed as needed.

4.2 Availability

4.2.1 Autoclave Cum Bung Processor **is intended to be operated: Regularly 2 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
- Installation, operation & maintenance Manual with spare List
- Warranty Certificate of machine ,
- Certificates & Manuals of brought out items including calibration
- Electrical circuit diagram, GA, P & ID protcols, drawings
- List of change parts

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
User ID Password

1) Engineering
2) Production
3) QA

4.5.3 Hardcopy/ electronic data collection both are required (Printer facility and electronic backup provision are required)

4.5.4 Data storage media-
; to all input/output values and system status bits shall be provided through a data-communication link. Security for data and operator access to provide by (User ID/Password)

4.5.5 User Interface with Supervisors and Operators

4.5.5.1 The CONTROL PLATFORM system shall include interfaces with the Operator and Supervisor that ensures easy, safe and reliable operation.

4.5.5.2 An-Operator- interface panel shall be provided and mounted near the equipment or on the equipment. This panel shall provide the necessary switches, indicators and devices to operate the equipment.

4.5.6 Language requirements
English

4.5.7 Display Requirements-
Measurement to be used-Metric (S.I.)

4.5.8 Interface with other equipment-

The control system shall include the interfaces necessary to facilitate operation and configuration-

- An RS-232 communications port shall be provided
- A Modem communications port shall be provided
- A high-speed configuration/ monitoring connection shall be provided

4.5.9 Data collection (archiving & reporting requirements)

- Recorder
- Electronic process printout, historical trending and interface to company network

The following shall be recorded
Product Name:
Batch No. /Lot No.
Process parameters prints

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 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:
Equipment/ system will not exceed 85 dB from 1meter

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 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				