USER REQUIREMENT SPECIFICATION

NAME OF THE ITEM: FURNITURE

FUNCTIONAL AREA: PRODUCTION

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			

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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 Instrument 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.

4.2 Purpose:

Furniture used in production area for the smooth work as per Requirement.

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5.0 USER REQUIREMENTS

5.1 System Requirements:

S.No.	SYSTEM COMPONENTS	SYSTEM REQUIREMENTS
1.	Identification	As per attached list
2.	Model/Type	As per cGMP Requirement
3.	Capacity	As per attached List
4.	Potential Suppliers	1. Visvakarma Resources 2. Allegro
5.	Contact parts	SS316 with mirror finish
6.	Non contact parts	SS304 with mirror finish 1. Any material with food grade quality having no Potential impact on the products. 2. Durable. 3. Must be easily cleanable.
7.	Packaging & Transport	Should be packed and transported in such a way to avoid any damage during transportation.
8.	No. of requirements	As per Attached List

5.2 Technical Description

S.No.	Specification	SYSTEM REQUIREMENTS
1.	Material of contact parts SS 316	YES
2.	Material of non contact parts SS 304	YES

6.0 COMPLEMENTARY ASPECTS

6.1 Pre Delivery Qualifications (FAT)

S.No.	Specification	SYSTEM REQUIREMENTS
6.1.1	FAT	NA

6.2 Supplier Technical Documentation Requirements:

S.No.	COMPONENTS	REQUIREMENTS
6.2.1	List of accessories	YES

7.0 SAFETY AND ENVIRONMENTAL PROTECTION

S.No.	Specification	Requirements
7.1	All Accessories must be in accordance with the cGMP.	YES

8.0 CLEANING MAINTENANCE AND SERVICE

S.No.	Specification
8.1	In accordance with cGMP guidelines the units must be easy to clean, to disinfect, and where necessary.
8.2	The design should be such as to allow mechanical cleaning of the surface and that the cleanliness of the surface can be checked easily.

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	Unload on site of the Furniture: The supplier is required to define all the necessary handling devices required to the unloading operation. The supplier will inform at least 2 weeks in advance the day of delivery and the list of required handling devices.	YES
10.2	A complete set of commissioning of Furniture's.	YES
10.3	All MOC Certificates in case of Contact part as specified in Attached List.	YES

11.0 INSTALLATION, COMMISSIONING AND TESTS

11.1 General

S.No.	Specification	Requirements
11.1.1	All furniture's as per User requirement	YES

11.2 INSTALLATION, COMMISSION

S.No.	Specification	Requirements
11.2.1	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
11.2.2	All the clearances and tolerances specified in the drawing or recommended by component manufacturers are correct.	YES
11.2.3	On site verification of all Furniture	YES

11.3 Site Acceptance Test (SAT)

S.No.	Specification	Requirements
11.3.1	Once the commissioning will be completed. The scope will be to verify the Requirements and the functionality of the accessories as per requirements.	YES
11.3.2	The functionality described in the User Requirements Specification and in the system specifications are verified and met.	YES

13.0 GAURANTEE/WARRANTEE

S.No.	Specification	Requirements
14.1	The furniture must be guaranteed.	YES
14.2	Furniture should be user friendly	YES