USER REQUIREMENTS SPECIFICATION – URS for

_____

Project No.: _____

TECHNICAL CONTENT			
Prepared by:	**Job title**	**Signature**	**Date**
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Reviewed by:	**Job title**	**Signature**	**Date**
QUALITY ASSURANCE			
Approved by:	**Job title**	**Signature**	**Date**

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REVISION HISTORY

Version that is changed	Reason for change	Version after the change	Date of validity

logo	**Document Title:** **USER REQUIREMENTS SPECIFICATION – URS for** _____	Document Number: _____ Version: Page:

1. Introduction

1.1 Purpose of Document:
Briefly describe the purpose of the URS and its significance in the procurement process.

1.2 Scope:
Define the scope of the equipment/system, including its intended use and the boundaries of the project.

2. Regulatory Compliance

2.1 Regulatory Standards:
List the regulatory standards and guidelines that the equipment must comply with (e.g., FDA, EMA, ISO).

3. User Requirements

3.1 Functional Requirements:
Detail what the equipment is expected to do, including operational parameters, capacity, and speed.

3.2 Performance Requirements:
Define the required performance levels, like efficiency, accuracy, and reliability.

4. Environmental and Operational Conditions

4.1 Environmental Requirements:
State the environmental conditions under which the equipment must operate.

5. Technical Specifications

5.1 Material of Construction:
Describe the materials required for the equipment.

5.2 Dimensions and Space Requirements:
Provide physical dimensions and space requirements.

5.3 Utility Requirements:
Outline the power, water, air, or other utility needs.

6. Criticality and Risk Assessment

6.1. Criticality
The criticality is performed in accordance to document _____. Include the parameter, the impact (direct, indirect…) and justification for that.

6.2. Risk Assessment
Determine the risk method in accordance to Risk Management Procedure. Determine the risk priority for each determined risk, having into consideration the likelihood of the risk, the severity of the risk and probability.

6.3. Testing Requirements
Based on the risks determined and their criticality, determine the testing requirements that should be performed.

7. Safety and Ergonomic Features

7.1 Safety Features:
List necessary safety features and ergonomic considerations for operators.

8. Quality and Compliance Features

8.1 Validation Requirements:
Describe the necessary validation processes (IQ, OQ, PQ).

8.2 Calibration and Maintenance:
Specify calibration, preventive maintenance, and breakdown maintenance requirements.

8.3 Documentation Requirements:
Detail required documentation for operation and maintenance.

9. Data Integrity and Control

9.1 Data Requirements:
Address requirements for data integrity, electronic records, audit trails, and security features.

10. Supplier and Vendor Requirements

10.1 Supplier Qualification:
Criteria for selecting and qualifying equipment suppliers.

10.2 Post-Installation Support:
Expectations for training, technical support, and warranty.

11. Budget and Cost Considerations

11.1 Budget Overview:
Provide an overview of budget constraints and cost considerations.

12. Delivery, Installation, and Commissioning

12.1 Delivery and Installation:
Detail expected delivery timelines and installation procedures.

12.2 Commissioning:
Outline commissioning process and criteria.

13. Acceptance Criteria

13.1 Acceptance Testing:
Define criteria for accepting the equipment after installation and validation.

14. Change Control and Revision Management

14.1 Change Management Process:
Outline the process for managing changes to the URS.

15. Appendices and Supporting Information

15.1 Additional Information:
Include any relevant diagrams, reference documents, and technical sheets.

Glossary

Glossary	
Acronym	**Definition**
°C	Degrees Celsius
CFR	Code of Federal Regulations
cGMP	common Good Manufacturing Practices
FAT	Factory Acceptance Test
FDA	Food and Drug Administration
GAMP	Good Automation Manufacturing Practices
HEPA	High Efficiency Particulate Array filter
EMA	European Medicines Agency
Hp	Horsepower
Hz	Hertz
SAT	Site Acceptance Test
SCADA	Supervisory Control and Data Acquisition
URS	User Requirement Specification
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
SOP	Standard Operating Procedure
WFI	Water For Injection