**User Requirements Specification (URS)**

**System**: LIMS  
**Version**: 1.0  
**Prepared By**: Durga Prasad K  
**Date**: 22-May-2025

**Document Control**

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| Version | 1.0 |
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**Approval Table**

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**Purpose**

To define user and business requirements for a potentiometric titration system interfaced with the Laboratory Information Management System (LIMS). The system will be used for assay, standardization, and endpoint detection of titrable pharmaceutical substances in the QC laboratory. All requirements support regulatory compliance, data integrity, and product quality.

**Scope**

This URS covers instrument software, associated hardware, and the data interface with LIMS. The system is GxP-relevant, categorized as GAMP 5 Category 4, and subject to full validation.

**📚 3. Definitions**

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| **Abbreviation** | **Definition** |
| URS | User Requirements Specification |
| CSV | Computer System Validation |
| GxP | Good Practices (e.g., GMP, GLP) |
| 21 CFR Part 11 | FDA regulation for electronic records & signatures |
| Annex 11 | EU guideline for computerized systems |

**✅ 4. User Requirements (Tabular Format)**

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| |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Traceability ID** | **User Dept** | **Requirement Description** | **Justification / Purpose** | **Acceptance Criteria** | **Priority** | **GxP Impact** | **Regulatory Reference** | | UR-001 | QC | Perform automatic titration for assay and standardization (e.g.,HCl, NaOH) | Accurate QC testing for APIs and solutions | System performs auto titration with validated precision | High | Yes | GAMP 5, ALCOA+ | | UR-002 | QC | Store test results securely | Ensure data retention and accuracy | Results stored with user ID, date/time | High | Yes | ALCOA+, 21 CFR Part 11 | | UR-003 | QC | Generate titration report with sample ID | Maintain traceability to batch/sample | Report contains sample ID, method, result | High | Yes | WHO GMP, ICH Q7 | | UR-004 | QC | Transfer results to LIMS automatically | Minimize manual entry, ensure accuracy | Verified result appears in LIMS batch record | High | Yes | 21 CFR Part 11, Annex 11 | | UR-005 | QC | Allow multiple methods for different sample types | Support various product and solution types | System supports user-defined titration methods | Medium | No | GAMP 5 Category 4 | | UR-006 | QA | Lock results once reviewed | Prevent post-review changes | Locked status appears after QA review | High | Yes | ALCOA+, 21 CFR Part 11 | | UR-007 | QA | Review & approval workflow (electronic/manual) | Controlled review process | System supports sequential review steps | High | Yes | 21 CFR Part 11 §11.100 | | UR-008 | QA | Audit trail for data changes | Maintain data integrity | System logs changes with timestamp, reason | High | Yes | ALCOA+, Part 11 §11.10(e) | | UR-009 | QA | 21 CFR Part 11 compliant electronic signatures | Enable electronic approvals | Signature includes name, date/time, reason | High | Yes | 21 CFR Part 11 §11.50 | | UR-010 | IT | Integration with LIMS server | Required for real-time data sync | LIMS interface successfully tested and documented | High | Yes | GAMP 5, Annex 11 | | UR-011 | IT | Secure login (user/password) | Restrict unauthorized access | Enforce password policy and role-based login | High | Yes | 21 CFR Part 11 §11.300 | | UR-012 | IT | Daily backup of results | Protect against data loss | Backup logs available and verified daily | High | Yes | Annex 11, ALCOA+ | | UR-013 | IT | Disaster recovery plan | Ensure system continuity | Documented DRP tested and approved | Medium | Yes | GAMP 5, ISO 27001 | | UR-014 | IT | Network folder for exported results | Simplify result retrieval by analysts | Exported files available in secure folder | Medium | No | Internal SOP | | UR-015 | RA | Data integrity compliance (ALCOA+) | Ensure GxP and regulatory compliance | System design supports all ALCOA+ principles | High | Yes | ALCOA+, WHO, FDA | | UR-016 | RA | Retention of results for 5–10 years | Align with regulatory expectations | Results archived and retrievable for 10 years | High | Yes | ICH Q7, WHO GMP | | UR-017 | RA | Traceability of test decisions | Support batch release and audit | Reports and logs show who made decisions | High | Yes | FDA Guidance, 21 CFR Part 11 | | UR-018 | Validation | System must be validated as GAMP 5 Category 4 | Required for GxP systems | Validation plan and summary report completed | High | Yes | GAMP 5 | | UR-019 | Validation | IQ/OQ/PQ must be performed | Prove installation and functionality | Signed protocols and reports filed | High | Yes | GAMP 5, EU Annex 15 | | UR-020 | Validation | Audit trail must be testable | Ensure audit readiness | Audit trail included in OQ test scripts | High | Yes | 21 CFR Part 11 | |  |  |  |  |  |  |  |
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