**Functional Requirement Specification (FRS)**

**System:** Potentiometric Titration System Interfaced with LIMS  
**Version:** 1.0  
**Prepared By:** Durga Prasad K  
**Date:** 24-May-2025

**1. Purpose**

The purpose of this Functional Requirements Specification (FRS) is to define the detailed functional behavior and operations of the Potentiometric Titration System interfaced with the Laboratory Information Management System (LIMS). This document serves as the foundation for system configuration, validation testing, and regulatory compliance.

**2. Scope**

This document covers all GxP-relevant functionalities of the titration system software, its LIMS interface, user workflows, data capture, report generation, security, and compliance-related features. This includes:

* Automatic titration
* Electronic records and signatures
* Audit trail
* User access and role management
* Result transfer to LIMS

**3. Definitions**

| **Term** | **Definition** |
| --- | --- |
| FRS | Functional Requirements Specification |
| LIMS | Laboratory Information Management System |
| CSV | Computer System Validation |
| GxP | Good Laboratory/Manufacturing Practices |
| ALCOA+ | Data integrity principles: Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available |

**4. Regulatory Compliance Summary**

This system and its functionality align with the following guidelines:

* **21 CFR Part 11**: Electronic signatures and records
* **EU Annex 11**: Audit trails, system validation
* **WHO GMP & ICH Q7**: Record retention, traceability
* **GAMP 5**: System lifecycle approach, Category 4 system
* **ISO 27001**: Backup and IT security practices

**5. Dependencies**

| **Dependency** | **Description** |
| --- | --- |
| URS | User-defined system requirements |
| TS | Technical design specifications |
| Risk Assessment | Functional Risk Assessment (FRA) to determine testing criticality |
| LIMS | Real-time connection to Lab Information System for result integration |

**6. Functional Requirements Table**

| **FR ID** | **Linked UR ID** | **Function Description** | **User Role** | **Acceptance Criteria** | **Priority** | **GxP Impact** | **Regulatory Ref** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| FR-001 | UR-001 | System shall perform automatic titration for assays and standardization | QC Analyst | Auto-titration executed with precise volume detection | High | Yes | GAMP 5, ALCOA+ |
| FR-002 | UR-002 | System shall store test results with metadata (user ID, date/time) | QC Analyst | Results stored securely and retrievable | High | Yes | 21 CFR Part 11, ALCOA+ |
| FR-003 | UR-003 | System shall generate titration reports including Sample ID and Method | QC Analyst | Report generated with traceable info | High | Yes | WHO GMP, ICH Q7 |
| FR-004 | UR-004 | System shall automatically transfer results to LIMS upon verification | IT/Validation | Verified data appears in LIMS | High | Yes | Annex 11, Part 11 |
| FR-005 | UR-005 | User-defined methods should be created and managed via GUI | QC Analyst | At least 3 methods configurable | Medium | No | GAMP 5 |
| FR-006 | UR-006 | Locking of result data after QA review | QA | Lock status appears in report | High | Yes | ALCOA+ |
| FR-007 | UR-007 | Electronic and manual approval workflows shall be supported | QA | Both review options enabled | High | Yes | 21 CFR Part 11 §11.100 |
| FR-008 | UR-008 | Audit trail must record data change events with timestamp and reason | QA/CSV | Viewable, testable audit trail | High | Yes | Part 11 §11.10(e) |
| FR-009 | UR-009 | System shall support 21 CFR Part 11-compliant e-signatures | All roles | Signatures logged with date/time | High | Yes | 21 CFR Part 11 §11.50 |
| FR-010 | UR-010 | System shall integrate with LIMS through a secure interface | IT | Successful connection with LIMS | High | Yes | GAMP 5, Annex 11 |
| FR-011 | UR-011 | Secure login with unique user/password credentials | All users | Enforced password policy | High | Yes | Part 11 §11.300 |
| FR-012 | UR-012 | Daily automatic backup of test results | IT | Backup logs auto-generated and stored | High | Yes | ALCOA+, ISO 27001 |
| FR-013 | UR-013 | Disaster recovery and restore functionality | IT | DRP tested and documented | Medium | Yes | GAMP 5 |
| FR-014 | UR-014 | Export of result files to secured network folder | QC | File accessible post-export | Medium | No | SOP Reference |
| FR-015 | UR-015 | ALCOA+ principles must be enforced in design | CSV/RA | Design evidence documented | High | Yes | ALCOA+, WHO GMP |
| FR-016 | UR-016 | Results retained for 10 years | RA | Archive logs available | High | Yes | ICH Q7, WHO GMP |
| FR-017 | UR-017 | Each decision step must be traceable | RA | Reports/logs show user, date, status | High | Yes | 21 CFR Part 11 |
| FR-018 | UR-018 | System shall be validated as GAMP 5 Cat 4 | CSV | Validation docs approved | High | Yes | GAMP 5 |
| FR-019 | UR-019 | IQ/OQ/PQ to be executed with signed reports | CSV | Protocols signed & filed | High | Yes | EU Annex 15 |
| FR-020 | UR-020 | Audit trail must be testable during OQ | QA/CSV | Audit test cases defined | High | Yes | 21 CFR Part 11 |

**7. Review & Approval Table**

| **Name** | **Designation** | **Department** | **Signature** | **Date** |
| --- | --- | --- | --- | --- |
| Venkata Ramana | QC Head | QC | \_\_\_\_\_\_\_\_\_\_\_ | 24-May-2025 |
| Bhavani | QA Head | QA | \_\_\_\_\_\_\_\_\_\_\_ | 24-May-2025 |
| Durga Prasad | CSV Analyst | IT Validation | \_\_\_\_\_\_\_\_\_\_\_ | 24-May-2025 |
| Likitha | RA Executive | RA | \_\_\_\_\_\_\_\_\_\_\_ | 24-May-2025 |

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