**Technical Specification (TS)**

**System:** Potentiometric Titration System Interfaced with LIMS  
**Version:** 1.0  
**Prepared By:** Durga Prasad K  
**Date:** 25-May-2025

**Document Control**

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| **Field** | **Value** |
| Document Title | Technical Specification (TS) for Potentiometric Titration System |
| Version | 1.0 |
| Prepared By | CSV Team |
| Date | 25-May-2025 |

**Approval Table**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name | Designation | Department | Signature | Date |
| Venkata Ramana | QC Head | QC | \_\_\_\_\_\_\_\_\_\_\_ | 25-May-2025 |
| Bhavani | QA Head | QA | \_\_\_\_\_\_\_\_\_\_\_ | 25-May-2025 |
| Durga Prasad | CSV Analyst | IT Validation | \_\_\_\_\_\_\_\_\_\_\_ | 25-May-2025 |
| Likitha | RA Executive | RA | \_\_\_\_\_\_\_\_\_\_\_ | 25-May-2025 |

**1. Purpose**

This Technical Specification (TS) defines the detailed technical architecture, interface, and configuration logic of the Potentiometric Titration System integrated with LIMS. It forms the basis for system implementation, installation, testing, and validation.

**2. Scope**

The TS covers the internal technical behavior and structure of:

* Instrument software and firmware
* Integration and communication layer with LIMS
* Security and access configurations
* Backup and disaster recovery mechanisms
* Audit trail, system logs, and encryption handling

**3. Definitions**

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| --- | --- |
| Term | Definition |
| TS | Technical Specification |
| API | Application Programming Interface |
| GUI | Graphical User Interface |
| DB | Database |
| XML/CSV | File formats used in integration |

**4. Compliance Summary**

This system follows the technical implementation as per:

* 21 CFR Part 11 (Electronic Records & Signatures)
* EU Annex 11 (Computerized Systems)
* GAMP 5 (Category 4 System)
* WHO GMP, ICH Q7
* ISO 27001 (IT security framework)

**5. Dependencies**

|  |  |
| --- | --- |
| Dependency | Description |
| URS | Source of business needs |
| FRS | Functional logic to be implemented technically |
| LIMS | System for result transfer and sample tracking |
| IT Infra | Network, backup servers, Active Directory setup |

**6. Technical Configuration Table**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| TS ID | Linked FR ID | Component | Technical Description | Data Flow | GxP Impact | Priority |
| TS-001 | FR-001 | Titration Engine | Supports potentiometric titration with electrode sensor inputs and auto burette control | Input from electrode → signal processor → burette | Yes | High |
| TS-002 | FR-004 | LIMS Interface | XML/CSV-based data exchange layer using REST API or file drop | Result → JSON/XML → Secure FTP → LIMS folder | Yes | High |
| TS-003 | FR-008 | Audit Trail | Technical logic to log field changes with user ID, timestamp, old/new value | Data → Encrypted audit DB → View audit module | Yes | High |
| TS-004 | FR-009 | E-signature Module | PKI or password-based digital signature stored in hash-encrypted format | Signature → Signature Table → Linked to record ID | Yes | High |
| TS-005 | FR-011 | Security Controls | Role-based access, minimum 8-char password, auto logout after 10 mins | Login → Auth engine → Role config table | Yes | High |
| TS-006 | FR-012 | Backup Schedule | Daily scheduled job using Windows Task Scheduler or Linux Cron | DB → Backup image → Encrypted cloud/server | Yes | High |
| TS-007 | FR-013 | Disaster Recovery | Virtualized image restoration and cold backup testing monthly | Recovery plan → Server reboot → Config restore | Yes | Medium |
| TS-008 | FR-014 | Export Function | Exports results as CSV/PDF to secure network folder with timestamp | Export → File write → Network folder access | No | Medium |
| TS-009 | FR-015 | ALCOA+ Enforcement | All data saved with traceable logs, versioning, and reviewer info | Data entry → Save → Log Version ID → Reviewer assign | Yes | High |
| TS-010 | FR-020 | OQ Audit Trail Testing | Specific test scripts to invoke audit trail and confirm entry recording | Input → Modify → View logs | Yes | High |

**7. Review & Approval Table**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name | Designation | Department | Signature | Date |
| Venkata Ramana | QC Head | QC | \_\_\_\_\_\_\_\_\_\_\_ | 25-May-2025 |
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