**Requirement Traceability Matrix (RTM)**

**System:** Potentiometric Titration System Interfaced with LIMS  
**Version:** 1.0  
**Prepared By:** Durga Prasad K  
**Date:** 27-May-2025

**1. Document Control**

|  |  |
| --- | --- |
| **Field** | **Value** |
| Document Title | Requirement Traceability Matrix (RTM) |
| Version | 1.0 |
| Prepared By | CSV Team |
| Date | 27-May-2025 |

**2. Review & Approval Table**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name | Designation | Department | Signature | Date |
| Venkata Ramana | QC Head | QC | \_\_\_\_\_\_\_\_\_\_\_ | 27-May-2025 |
| Bhavani | QA Head | QA | \_\_\_\_\_\_\_\_\_\_\_ | 27-May-2025 |
| Durga Prasad | CSV Analyst | IT Validation | \_\_\_\_\_\_\_\_\_\_\_ | 27-May-2025 |
| Likitha | RA Executive | RA | \_\_\_\_\_\_\_\_\_\_\_ | 27-May-2025 |

**3. Objective**

The Requirement Traceability Matrix (RTM) ensures that each user requirement is traced to its corresponding functional requirement, technical design, test case, and qualification activity. It provides proof of coverage, alignment with risk assessments, and confirms testing validation.

**4. Traceability Table**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| URS ID | FRS ID | TS Ref | Test Case ID | GxP Impact | FRA ID | Risk Level | Qualification Type | Regulatory Ref |
| UR-001 | FRS-001 | TS-001 | TC-001 | Yes | FRA-001 | High | OQ/PQ | GAMP 5, ALCOA+ |
| UR-002 | FRS-002 | TS-002 | TC-002 | Yes | FRA-003 | High | OQ | 21 CFR Part 11 |
| UR-003 | FRS-003 | TS-003 | TC-003 | Yes | FRA-001 | High | PQ | ICH Q7, WHO GMP |
| UR-004 | FRS-004 | TS-004 | TC-004 | Yes | FRA-002 | High | OQ/PQ | Annex 11, Part 11 |
| UR-005 | FRS-005 | TS-005 | TC-005 | No | FRA-008 | High | OQ | GAMP 5 Cat 4 |
| UR-006 | FRS-006 | TS-006 | TC-006 | Yes | FRA-003 | High | PQ | ALCOA+ |
| UR-007 | FRS-007 | TS-007 | TC-007 | Yes | FRA-003 | High | PQ | Part 11 §11.100 |
| UR-008 | FRS-008 | TS-008 | TC-008 | Yes | FRA-003 | High | OQ | Part 11 §11.10(e) |
| UR-009 | FRS-009 | TS-009 | TC-009 | Yes | FRA-004 | High | PQ | 21 CFR Part 11 §11.50 |
| UR-010 | FRS-010 | TS-010 | TC-010 | Yes | FRA-002 | High | OQ | GAMP 5, Annex 11 |
| UR-011 | FRS-011 | TS-011 | TC-011 | Yes | FRA-005 | High | IQ/OQ | 21 CFR Part 11 |
| UR-012 | FRS-012 | TS-012 | TC-012 | Yes | FRA-006 | High | OQ | ALCOA+, Annex 11 |
| UR-013 | FRS-013 | TS-013 | TC-013 | Yes | FRA-010 | High | IQ/OQ | ISO 27001 |
| UR-014 | FRS-014 | TS-014 | TC-014 | No | FRA-007 | Medium | OQ | Internal SOP |
| UR-015 | FRS-015 | TS-015 | TC-015 | Yes | FRA-003 | High | PQ | WHO, ALCOA+ |
| UR-016 | FRS-016 | TS-016 | TC-016 | Yes | FRA-009 | High | PQ | ICH Q7 |
| UR-017 | FRS-017 | TS-017 | TC-017 | Yes | FRA-003 | High | PQ | FDA, Part 11 |
| UR-018 | FRS-018 | TS-018 | TC-018 | Yes | FRA-001-FRA-010 | High | VMP / Summary | GAMP 5 |
| UR-019 | FRS-019 | TS-019 | TC-019 | Yes | FRA-001-FRA-010 | High | IQ/OQ/PQ | Annex 15 |
| UR-020 | FRS-020 | TS-020 | TC-020 | Yes | FRA-003 | High | OQ | 21 CFR Part 11 |