**SECTION A:**

|  |  |  |  |
| --- | --- | --- | --- |
| CCR No. |  | Date of issuance |  |
| Applicable to |  Area Utility Product System Document   Equipment Material Instrument Other   |  T.C.D. |  |
|  Ext. I |  |
| Title of Change |  | Ext. II |  |
| Product / material / Document / Instrument/Equipment/Area/Utility/Other |  | Reference Batch No./AR No. /Doc. No./Equipment ID /Instrument ID/Area |  |
| Previous change control form No.(if any) |
| Initiated By(Name) |  |  Logged By QA (Name) |  |
| Department |  |
| **CHANGE DETAILS** |
| Existing system |
|  |

 **CCR No.:**

|  |
| --- |
| Proposed change |
|  |
| Justification |
|  |
| Initiated by(Sign & Date) |  | Approved by HOD/Designee(Sign & Date) |  |

**SECTION B:**

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| --- |
| **IMPACT ANALYSIS** |
| Items | Impact (Yes/No) | Action Item No. | Recommendation of Impacted Dept. HOD/ Designee | Concerned HOD(Sign & Date) |
| Process |  |  |  |  |
| Quality Parameter |  |  |  |  |
| Calibration Schedule |  |  |  |  |

**CCR No.:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items | Impact (Yes/No) | Action Item No. | Recommendation of Impacted Dept. HOD/ Designee | Concerned HOD(Sign & Date) |
| Stability |  |  |  |  |
| Process Validation |  |  |  |  |
| Cleaning Validation  |  |  |  |  |
| Training |  |  |  |  |
| Information(As per annexure 7) |  |  |  |  |
| Hold time Sampling |  |  |  |  |
| Regulatory Approval  |  |  |  |  |
| Mfg. product Lic./COPP |  |  |  |  |
| Marketing Approval |  |  |  |  |
| DCGI |  |  |  |  |
| Product list |  |  |  |  |
| Cleaning/Passivation/Sanitation |  |  |  |  |
| Preventive Maintenance Schedule  |  |  |  |  |
| Equipment / Instrument Master List |  |  |  |  |
| Layout/ Drawing/ Diagram |  |  |  |  |
| Segregation of the Area/ Caution Display |  |  |  |  |
| Utility Impact |  |  |  |  |
| Spec./ATP (RM, PM,FP, stability) |  |  |  |  |

**CCR No.:**

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| --- | --- | --- | --- | --- |
| Items | Impact (Yes/No) | Action Item No. | Recommendation of Impacted Dept. HOD/ Designee | Concerned HOD(Sign & Date) |
| MBMR / Mfg. BOM |  |  |  |  |
| MBPR / Pkg. BOM |  |  |  |  |
| SOP / Protocol |  |  |  |  |
| LIMS / METIS/SAP |  |  |  |  |
| Qualification |  |  |  |  |
| Calibration |  |  |  |  |
| Packing Material/ Pack style |  |  |  |  |
| Change parts / tooling |  |  |  |  |
| Artwork |  |  |  |  |
| Rejection / Destruction |  |  |  |  |
| Price, equipment list |  |  |  |  |
| E.H.S.(If yes annexure) |  |  |  |  |
| Risk Assessment  |  |  |  |  |
| Cross function investigation report  |  |  |  |  |
| CAPA  |  |  |  |  |
| MSTG/FDD Comment |  |  |  |  |
| Any Other |  |  |  |  |
| Dep. Head(Sign & Date) |  |
| Impact Analysis Review by QA Head /Designee(Sign and Date) |  |

**CCR No.:**

|  |  |  |
| --- | --- | --- |
| **Notification** | **Comment** | **Sign & Date** |
| Plant Head |  |  |
| **SECTION C:**  |  |
| **Approval for execution** |
| **To be filled by QA Head/Designee** Approved Rejected Change Review Level:  Level I  Level II  Level III |

|  |  |  |
| --- | --- | --- |
| Approved By | Comment | Sign & Date |
| Department Head / Production Head |  |  |
| Q.A. Head |  |  |
| Site Quality Head |  |  |

**SECTION D:**

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| **ACTION ITEM CLOSURE DETAILS** |
| Action Item Number | Action Item Completion Date | Initiator/DesigneeSign and Date | Reference Document Details | Reviewed By QASign and Date |
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 **CCR No.:**

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| Action Item Number | Action Item Completion Date | Initiator/DesigneeSign and Date | Reference Document Details | Reviewed By QASign and Date |
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| **ACTION ITEM CLOSURE EVALUATION** |
| **Department** | **Comments** | **Sign & Date** |
| Department Head |  |  |
| Quality Assurance |  |  |

**SECTION E:**

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| **IMPLEMENTATION AND CHANGE CLOSURE DETAILS** |
| **Change implemented Change not implemented**  |
| **Closure comments:** |
| **Post changes review requirement (PCRR)** |  Yes  No  |
| **Recommendation for PCRR:** |
| **Checked by QA Head****(Sign & Date)** | **Approved by Site Quality Head****(Sign & Date)** |
|  |  |

 **CCR No.:**

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| --- | --- |
| **Change control closer status:**  **Closed**  **Not implemented** | **Sign and Date** |
|  |

**SECTION F:**

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| **POST CHANGES AND EFFECTIVENESS MONITORING DETAILS** |
| **Mode : APQR / Protocol / Self Inspection / CAPA** | **Reference Tracking No.:** |  |
| **Target Date** |  |
| **Date & Sign** |  |
| Date | Observation | Final conclusion | Ref. Doc. No. | Checked bySign and Date |
|  |  |  |  |  |
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**Documents Attached:**

1.

2.

3.

4.

5.