**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.:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ACTION ITEM CLOSURE DETAILS** | | | | |
| Action Item Number | Action Item Completion Date | Initiator/Designee  Sign and Date | Reference Document Details | Reviewed By QA  Sign and Date |
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**CCR No.:**

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

**SECTION E:**

|  |  |  |
| --- | --- | --- |
| **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.:**

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

**SECTION F:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 by  Sign and Date |
|  |  |  |  |  |
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**Documents Attached:**

1.

2.

3.

4.

5.