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| **Change Control No.** |  | **Change Control Issued by (Name / Dept.)** |  |
| **PART-I INITIATION OF CHANGE CONTROL** | | | |
| ***(Section 1.0)* Initiator Department** | | | |

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| **Initiated by**  **(Name & Sign)** |  | **Date of issuance** |  |
| **Department** |  | **Section** |  |
| **Name of Product/ Document** |  | **Batch No. /**  **Document No.** |  |

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| ***(Section 2.0)* Change Requested for** | | | | | | | | | |
| **Change Requested for** | | Procedure Specifications / Analytical Procedure Facility  Raw / Packing Materials Equipment Documents Utilities  Manufacturing Process Other or as per Annexure (SOP/QA/003-F06)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | |
| ***(Section 3.0)*** ***Standard current Procedure/ document (s) or existing procedure/ document (s):*** | | | | | | | | | |
| *Note: Attach supportive evidence/documents (as applicable):* | | | | | | | | | |
| ***(Section 4.0)*** ***Details of change (s) proposed:*** | | | | | | | | | |
| *Note: Attach supportive evidence/data/documents (as applicable):* | | | | | | | | | |
| ***(Section 5.0)*** ***Justification for proposed change (s):*** | | | | | | | | | |
| *Note: Attach supportive evidence/data/documents (as applicable):* | | | | | | | | | |
| ***(Section 6.0)* Change Affected Documents: (attached separate sheet if required)** | | | | | | | | | |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **S. No.** | **Document No.** | **Document Title** | **Effective Date** | **Type of Impact Amended/Cancelled** | **Tentative date of change Implementation** | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | | **Tentative Date of closing:** | | | | | | | **Remark if any-** | | | | | | | **Concern HOD/designee comments:**  **Concern HOD /Designee (Sign/Date):** | | | | | | | | | | | | | | | |
| |  |  |  | | --- | --- | --- | | ***(Section 7.0) Signature of initiating department*** | | | | Name | **Change Initiated By** | **Authorized By**  ***(Head/Designee of initiating department)*** | |  |  | | **Signature** |  |  | | **Date** |  |  | | | | | | | | | | |
| **PART-II (A) CHANGE CONTROL FORM CONSENT & REVIEW** | | | | | | | | | |
| ***(Section 8.0)* Change Control Form circulated to following departments** | | | | | | | | | |
| **Engineering Personnel & Administration**  **Production EHS**  **Quality Control Warehouse**  **Microbiology IT**  **Human Resources Regulatory Affairs**  **Others** | | | | | | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **QA (Sign/Date)** | | | |
| ***(Section 9.0)* Consent of concerned department & other departments (write NA if not applicable)** | | | | | | | | | |
| **9.1 Review Comments** | | | | | | | | | |
| **Department** | | **Review Comments**  ***(Attach additional sheet for more details if required)*** | | | | | **Change Accepted/**  **Not accepted** | | **Reviewed by**  **(HOD/Deputy)** |
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| **Scope of Change**  ***(Tick whichever is applicable)*** | | | | **C01 C02 C03 C04 C05** | | | | | |
| ***(Section10.0)* PART-II (B) CHANGE CONTROL ASSESSMENT BY QA** | | | | | | | | | |
| **Level of change**  *(Tick whichever is applicable)* | | **Type – A (Minor):** Minor changes who do not have any detectable impact on the quality attributes of the product and having no regulatory impact. | | | | | | |  |
| **Type – B (Major):** Changes that are likely or may have minor impact on the quality attributes of the product like Major change in BPCR, MFR. Specification addition & deletion of any test requires intimation to Regulatory agency and Marketing Authority / Customer | | | | | | |  |
| **Type – C (Critical):** Changes that are having significant impact on the quality attributes of the product like Major change in BPCR, MFR. Specification addition & deletion of any test change in validated parameter. And requires pre-approval from the registration agency and marketing Authority / Customer. | | | | | | |  |
| ***(Section11.0)* Impact on Regulatory Affairs and Marketing Authority / Customer** | | | | | | | | | |
| ***Applicable for Type –B & Type C (but not limited to)*** | | | | | | | | | |
| **Review Comment** | | |  | | | | | | |
| **Conclusion** | | | **Approved Not Approved** | | | | | | |
| **Impact Evaluated By *(Representative of RA department)*** | | | | | | | | | |
|  | | |  | | | | | |  |
| **Name** | | | **Signature** | | | | | | **Date** |
| ***(Section 12.0)* Action to be Carried Out for the Proposed Change** | | | | | | | | | |
| **S. No.** | **Action** | | | | **Tentative date of completion** | | | **Sign/Date** | |
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| ***(Section 13.0)* Reviewed by QA** | | | | |
| **S. No.** | **Action** | | **Check point** | |
| 1. | Whether all related documents are drafted and evaluated. | | **Yes No NA** | |
| 2. | All related departments are intimated. | | **Yes No NA** | |
| **QA Representative comment:-** | | | | |
| **Change Evaluated By (Representative of QA department)** | | | | |
|  | |  | |  |
| **Name** | | **Signature** | | **Date** |
| ***(Section 14.0)* PART – III: APPROVAL OF CHANGE BY HEAD QA /DESIGNEE** | | | | |
| **(*Put tick which ever applicable*)** | | **€ Approved € Rejected** | | |
| **Commented by Head QA/Designee:**  **Head QA/Designee (Sign/Date):** | | | | |
| **Justification if rejected CCF:**    **Head QA/Designee (Sign/Date):** | | | | |

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| ***(Section 15.0)* PART – IV: MONITORING, FOLLOW UP AND CLOSURE OF CHANGE** | | | | | | | |
| **Extension on Tentative close Date (TCD) (if Applicable) (Refer change control TCD extension Form)** | | |  | | | **QA (Sign/Date)** |  |
| **Extension on Alternate Tentative close Date (ATCD) (if Applicable) (Refer change control TCD extension Form)** | | |  | | | **QA (Sign/Date)** |  |
| ***(Section 16.0)* Change Implementation Checklist** | | | | | | | |
| **S. No.** | **Action** | | **Check Point** | | | | |
| 1. | The change is implemented as proposed. | | **Yes No NA** | | | | |
| 2. | Training is completed and evaluated to all concerned | | **Yes No NA** | | | | |
| 3. | Others, Specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | **Yes No NA** | | | | |
| 4. | Change effective from & date | |  | | | | |
| **Initiating Department Head (Sign / Date):** | | | | | | | |
| ***(Section 17.0)* QA Assessment checklist** | | | | | | | |
| **S. No.** | **Document type** | | | **Review** | | **Existing Reference No.** | **Revised Reference No.** |
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| ***(Section 18.0)* ClosinChecklist** | | | | | | | |
| **S. No.** | **Action** | | | **Check Point** | | | |
| 1. | Whether all applicable documents are revised, distributed, and implemented. | | | **Yes No NA** | | | |
| 2. | All the superseded documents are retrieved, made obsolete, and destroyed. | | | **Yes No NA** | | | |
| 3. | The change is implemented as proposed. | | | **Yes No NA** | | | |
| 4. | Training is completed and evaluated to all concerned | | | **Yes No NA** | | | |
| 5. | The qualification/validation/stability as applicable is initiated as recommended. | | | **Yes No NA** | | | |
| 6. | Others, Specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | **Yes No NA** | | | |
| 7. | After three extension TCD/ATCD, if CCF not closed within 90 days then CAPA shall be remain open whereas CCF shall be closed and new CCF shall be initiated by concerned department. | | | **Yes No NA** | | | |
| 8 | CAPA No. (if any) | | |  | | | |
| 9 | Change Control Implementation Status and Closer | | | **Change Implemented**  ***Change Not Implemented*** | | | |
| 10 | Change effective from Product Name/Doc. Name | | |  | | | |
| 11 | Change effective from Batch No./Equip./Instru. No. | | |  | | | |
| 12 | Change effective from Document No. | | |  | | | |
| 13 | Change Control Closure Date | | |  | | | |
| Name | | **Change Reviewed By QA** | | | **Change Closed By *(Head -QA)*** | | |
|  | | |  | | |
| **Sign** | |  | | |  | | |
| **Date** | |  | | |  | | |