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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)** |
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| **S. No.** | **Document No.** | **Document Title** | **Effective Date** | **Type of Impact Amended/Cancelled** | **Tentative date of change Implementation** |
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| **Tentative Date of closing:** |
| **Remark if any-** |
| **Concern HOD/designee comments:** **Concern HOD /Designee (Sign/Date):** |

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| ***(Section 7.0) Signature of initiating department*** |
| Name | **Change Initiated By** | **Authorized By*****(Head/Designee of initiating department)*** |
|  |  |
| **Signature** |  |  |
| **Date** |  |  |

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| **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** |  |  |