|  |  |
| --- | --- |
| **Change Control Form No:**(To be filled by QA Dept.) | **Date:** |
| **Originating Department**  | **:** |  |
| **Originator**  | **:** | -------------------------------------- Name | -------------------------------------- Sign and Date  |
| **Department**  | **:** |  |
| **Market Details**  | **:** |  |
| **Product Name**  | **:** |  |
| **Change Related to** | **:** | Tick (√) whatever applicable  |
| Master Formula Card/Record |  | Batch Numbering System |  | SOPs |  | Cleaning Validation |  |
| Batch Manufacturing Record |  | Raw Material Active |  | Format |  | Process Validation |  |
| Master Packing Card/Record |  | Raw Material Excipients |  | Equipment |  | Analytical Method Validation |  |
| Batch Packing Card/Record |  | Vendor |  | Process |  | Master Validation plan |  |
| Packing Primary |  | Specification |  | Utilities |  | Site Master File |  |
| Packing Secondary |  | Standard Analytical Specification |  | Equipment Qualification |  | Computer System |  |
| Artwork |  | Stability |  | Utilities Qualification |  | Regulatory Filling |  |
|  |  | Shelf life |  | Area Qualification |  | Others |  |
| **Existing Procedure:** |
| **Proposed change:****Reason For Changes:****Primary Review and comments By Department Head :**  **This proposal is Recommended ** / Not Recommended **  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **(Name) (Signature & Date)** |
| **Research and development Department:** |
| **Evaluation by R&D (tick(√) whatever applicable)**

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| Validation required |  | Validation not required |  |   |
| Market approval required |  | Market approval not required |  |   |

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| **Comments:** **Approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **(Name) (Signature & Date)** |
| **Review by Additional Departments:** |
| **Department Name** | **Comments** | **Approval** |
| **Name** | **Signature** | **Date** |
| **Quality Assurance** |  |  |  |  |
| **Quality Control** |  |  |  |  |
| **Stores** |  |  |  |  |
| **Production** |  |  |  |  |
| **Engineering**  |  |  |  |  |
| **Microbiology** |  |  |  |  |
| **Personal and Administration** |  |  |  |  |
| **Regulatory Affairs** |  |  |  |  |
| **R&D** |  |  |  |  |
| **Safety** |  |  |  |  |
| **Review by Customer/Contract Manufacturing Party : (If Applicable)** |
| **Comments:****Approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **(Name and Designation) (Signature & Date)** |
| **Quality Assurance Department :****Head QA/Designee:** |
| **Training required ( ) Training not required ( )**  |
| **Training to be imparted to departments:**1. **Quality Assurance ( ) 2) Quality Control ( ) 3) Production ( )**
2. **Stores ( ) 5) Research and Development ( ) 6) Regulatory Affairs ( )**

**7) Microbiology ( ) 8)Personal and Administration ( ) 9) Engineering ( )** |
| **The change request is Approved ( ) Rejected ( )**  |
| **Whether the change proposal is Minor ( ) Major ( ) Critical ( )** |
| **Information send to Customer Yes ( ) No ( ) NA ( )** |
| **Comments:** |
| **Final Review and Approval** **Head QA/Designee \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **(Name) (Signature & Date)** |
| **Implementation Details** |
| **Change implemented on :**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **(Name) Department (Signature & Date)** |
| **Closure of Change Control Form: (To be filled By QA)** |
| **Related Documents Revised as per change Yes ( ) No ( )**  **If Yes Document No.: Version No.:** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **(Name) (Department) (Signature & Date)** |