|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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)**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Validation required |  | Validation not required |  |  | | Market approval required |  | Market approval not required |  |  | | | | | | | | | | | | | | |
| **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)** | | | | | | | | | | | | | |