##### ANNEXURE – 1

|  |  |  |
| --- | --- | --- |
| CHANGE CONTROL FORM | | |
| Initiated by | Department | Date |
|  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| CHANGE REQUESTED | | | | | | |
| **Please mark (🗸) wherever is applicable** | | BPRR BPAR SOP Master Formula Analytical Method Formats Specifications STP GTP  Artwork Facility Utility New Equipment others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| Title | |  | | | | |
| S.No. | Existing \* | | | Proposed Changes\* | **Reason For Changes\*** | **Evaluation\***  **(To be filled by Department Head)** |
|  |  | | |  |  |  |
| **Supportive Documents (If any)** | | | |  | **Evaluated by (Sign &Date)** |  |
| Categorising  the change: | | | (A) No Regulatory Impact (B) Minor Changes Involving the Registration Agency Approval  (C) Major Changes Involving Registration Agency Approval | | | |
| Other departments comments required: Yes No Regulatory Comments required: Yes No  Name of the Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ To be filled by Change Control Coordinator for categorising the change] | | | | | | |

\* Attach additional sheet for more details if required

Form No. – APL/QA/F008-03/ 07-2003 Page No: 1 of 3

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| CHANGE CONTROL FORM | | | | | | | |
| **OTHER DEPARTMENTS REVIEW** | | | | | | | |
|  | | | | | | | |
| **Reviewed By : (Name)** | | | Department | | **Sign** | **Date** | |
|  | | |  | |  |  | |
| **OTHER DEPARTMENTS REVIEW** | | | | | | | |
|  | | | | | | | |
| **Reviewed By : (Name)** | | | Department | | **Sign** | **Date** | |
|  | | |  | |  |  | |
| REGULATORY AFFAIRS COMMENTS | | | | | | | |
| Assessment of  Regulatory Impact | **Approved Not Approved Required Approval from Regulatory Agency**  **Annual Reportable Changes Validation required but changes could be implemented till Regulatory Agency approval** | | | | | | |
| Comments (if any) | | | | | | | |
| **Reviewed By : (Name)** | | | Department | | **Sign** | **Date** | |
|  | | |  | |  |  | |
| **EVALUATION AND CONCLUSIONS (CHANGE CONTROL COORDINATOR)** | | | | | | |
|  | | | | | | |
| Evaluation by | | Sign & Date | |  | | |

Form No. – APL/QA/F008-03/ 07-2003 Page No: 2 of 3

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| CHANGE CONTROL FORM | | | | | | | | | | | |
| **CONCLUSIONS AND RECOMMENDATIONS BY HEAD – QA & RA** | | | | | | | | | | | |
|  | | | | | | | | | | | |
| **Changes** | | | **Accepted Rejected** | | | | | | | | |
| **Reviewed By : (Name)** | | | Sign | | | | | **Date** | | | |
|  | | |  | | | | |  | | | |
| **Change Control Number** | | | **Allotted Date** | | | | | **Allotted by** | | | |
|  | | |  | | | | |  | | | |
| **Effective Date for above changes** | | | | | |  | | | | | |
| **DOCUMENTS AFFECTED BY THE CHANGE (BY DOCUMENTATION CELL)** | | | | | | | | | | | |
| **S.No.** | **Document Title** | | | **Document no.** | | | **Document changed** | | | | **Date of change** |
|  |  | | |  | | |  | | | |  |
|  |  | | |  | | |  | | | |  |
|  |  | | |  | | |  | | | |  |
|  |  | | |  | | |  | | | |  |
|  |  | | |  | | |  | | | |  |
| Please mark (🗸) wherever is applicable | | **Training Required, Validation Required, Stability Studies Required**  **Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | |
| Change Control Coordinator Sign and date: | | | | | | | | | |
| DOCUMENTATION | | | | | | | | | | | |
| Training done on | | | | |  | | | | | **Sign:**  **Date:** | |
| **Validation Completed On** | | | | |  | | | | | **Sign:** | |
| **Stability Studies Initiated on** | | | | |  | | | | | **Sign:**  **Date:** | |
| **Others if any** | | | | |  | | | | | **Sign:**  **Date:** | |
| **Documentation Controller** | | | | |  | | | | | **Sign:**  **Date:** | |
| **DCR / FCR - DISPOSED / NOT DISPOSED** | | | | | **Sign & Date (Change Control Coordinator)** | | | |  | | |

Form No. – APL/QA/F008-03/ 07-2003 Page No: 3 of 3