##### 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)** |  |
| Categorisingthe 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 NoName 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 ofRegulatory 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