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| **Record the observations in the columns given next to the relevant points in checklist by giving a (✓) mark or (×) mark depending on the nature of the observation.** | | | | |
| **SELF INSPECTION CHECK LIST** | | **DEPARTMENT: QUALITY ASSURANCE** | | |
| 1. **Standard Operation Procedure**   (ISO 22000:2005 – 4.2)  (ISO 9001:2008 – 4.2)  (ISO 22716:2008 – 17)  (EU GMP Volume 4, Part 1, Chapter 8, 8.2, 8.10) | | | | |
| 1.1 | All the SOPs are within the valid period of review. | |  |  |
| 1.2 | All the SOPs filed and distributed to the respective department are the copies of current version of Master Copy. | |  |  |
| 1.3 | SOPs for all the activities performed are available. | |  |  |
| 1.4 | Master SOP index of all departments are available. | |  |  |
| 1.5 | Change Controls register Updated with relavent details. | |  |  |
| 1.6 | Market Complaint register Updated with relavent details. | |  |  |
| 1.7 | All market complaints are closed with the appropriate investigation and a proper justification. | |  |  |
| 1.8 | Planned deviations and unplanned deviations verified and closed and entered in the register/file. | |  |  |
| 1.9 | Incident Reports and Non Conformances verified and closed and entered in the register/file. | |  |  |
| 10.0 | A recall procedure is in place to recall any batch of the product from sale or supply. | |  |  |
| **2.0 Document Control**  (ISO 22000:2005 – 4.2)  (ISO 9001:2008 – 4.2)  (ISO 22716:2008 – 17)  (EU GMP Volume 4, Chapter 5, 5.40)  (EU GMP Volume 4, Chapter 4, 4.7, 4.8, 4.9, 4.17, 4.29) | | | | |
| 2.1 | Superseded Copies of Documents stamped with “SUPERSEDE COPY” and filed properly. | |  |  |
| 2.2 | All Superseded Copies of Documents filed and kept under lock and key. | |  |  |
| 2.3 | Have validations been completed and documented as per Master Validation Plan? | |  |  |
| 2.4 | All the files & register maintained are assigned register/file number | |  |  |
| 2.5 | Are maintaining Data logger details? | |  |  |
| **3.0 Training**  (ISO 22000:2005 – 6.2.2)  (ISO 9001:2008 – 6.2.2)  (ISO 22716:2008 – 3.4, 3.6)  (EU GMP Volume 4, Chapter 4, 4.20, 4.21)  (EU GMP Volume 4, Part 1, Chapter 2, 2.8, 2.9, 2.10) | | | | |
| 3.1 | Is Training Schedule is available? | |  |  |
| 3.2 | Training Records updated with respect to Trainning Schedule. | |  |  |
| 3.3 | Separate file is available for planned and unplanned training. | |  |  |
| 1. **Batch Records**   (ISO 22000:2005 – 4.2.3)  (ISO 9001:2008 – 4.2.4)  (EU GMP Volume 4, Part 1, Chapter 6, 6.12, 6.13) | | | | |
| 4.1 | The Batch Records Issue Register updated with relavent details | |  |  |
| 4.2 | Review of Batch Record are as per the procedure. | |  |  |
| 4.3 | Is the product release is as per SOP? | |  |  |
| 4.4 | Are the Analytical Reports and COA attached with the respective Batch Records? | |  |  |
| 4.5 | Are Batch Records reviewed as per the approved check list? | |  |  |
| 4.6 | Reconcilliation of the batches satisfactory. | |  |  |
| 4.7 | Is filled check list attached with the respective Batch Records? | |  |  |
| 4.8 | All reviewed Batch Records kept safely. | |  |  |
| 4.9 | Release of every product batch/s is being done after approval of QP. | |  |  |
| 1. **Management Representative Functions**   (ISO 9001:2008 – 5.5.2)  (ISO 22000:2005 – 5.0) | | | | |
| 5.1 | All the defined MR functions are executed and recorded. | |  |  |