|  |  |
| --- | --- |
| **CAPA Report** | |
| **CAPA Number**  (to be assigned by Quality Organization) |  |
| **CAPA Owner**  Name/Date/Signature |  |
| **Related documents**  (Deviations/OOS/Complaints/Quality Defects investigation reports, audit reports, risk assessments, process/product/system reviews, Change records), if any |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **CAPA description** | | | |
| **Corrective Action  Preventive Action** | | | |
| **Action description** | | | |
| Start Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Planned end date\_\_\_\_\_\_\_\_\_\_ | | Completion Date\_\_\_\_\_\_\_\_\_\_\_ |
| **CAPA Owner** | | Name/Date/Signature | |
| **Comments** | | | |

|  |  |
| --- | --- |
| **Deviations** | |
| **Implementation timeline deviations justification, if any** | |
| **Timeline deviation approved by**  Quality Organization representative | Name/Date/Signature |
| **Comments** | |

|  |  |
| --- | --- |
| **Effectiveness Monitoring** | |
| **Required (Corrective Action)  Not Required (Preventive Action)** | |
| **CAPA Effectiveness Criteria** (for Corrective Actions only) | |
| **CAPA implementation documented evidences** (List of documents or other information) | |
| **CAPA Effectiveness Monitoring summary** | |
| **Corrective Action is effective** | **YES  NO** |
| **Corrective Action/Preventive Action is closed** | **YES  NO** |
| **Further actions required, if any** |  |
| **Quality Organization representative** | Name/Date/Signature |
| **Comments** | |