|  |
| --- |
| **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** [ ]  **n/a** |
| **Corrective Action/Preventive Action is closed** | [ ]  **YES** [ ]  **NO** |
| **Further actions required, if any** |  |
| **Quality Organization representative** | Name/Date/Signature |
| **Comments** |