**Complaint Investigation Plan**

|  |
| --- |
| **Product details** |
| **CRN** |  |
| **Notification Date** |  |
| **Product** |  |
| **Strength of drug product** |  |
| **Lot/Batch number** |  |
| **Manufacturing date** |  |
| **Expiry date** |  |
| **Product packaging details** |  |
| **Description of complaint** |  |
| **Preliminary Quality Defect Classification** | [ ]  **Class 1** [ ]  **Class 2** [ ]  **Class 3** |
| **Supposed Reasons** |
| [ ]  **Wrong application** [ ]  **Manufacturing issue** [ ]  **Quality Control issue**[ ]  **Quality Release issue** [ ]  **Marketing Authorization issue**[ ]  **Supply Chain issue** [ ]  **Storage condition issue**[ ]  **Counterfeit suspicion** [ ]  **not defined** |

|  |
| --- |
| **Scope of investigation** |
| **Departments/functions/processes to be involved** |
| **What areas should be investigated** |
| Department 1 |  |
| Department 2 |  |
| **What data should be collected and provided** |
| Department 1 |  |
| Department 2 |  |
| **What actions should be taken and expected timelines** |
| Department 1 | Action/Due Date |
| Department 2 | Action/Due Date |
| **What questions should be answered** |
| Department 1 |  |
| Department 2 |  |

|  |
| --- |
| **Proposed measures** |
| **Product shipment Return** | [ ]  **YES** [ ]  **NO** |
| **Product Recall** | [ ]  **YES** [ ]  **NO** |
| **Segregation/Quarantining measures** | [ ]  **YES** [ ]  **NO** |
| **Competent authorities notification** | [ ]  **YES** [ ]  **NO** |
| **Comments:** |

|  |
| --- |
| **Complaint Investigation Plan consent**(to be signed off by all representatives involved departments and functions) |
| SME | Date/Signature |
| SME | Date/Signature |
| e.g., e.g., Quality Management Director | Date/Signature |