**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., Quality Management Director | Date/Signature |