|  |  |
| --- | --- |
| **{{ ComplaintPrelimAssess }}** | |
| **CRN** |  |
| **Notification Date** |  |
| **Complaint Category**  Note: If potential ADE is suspected, a Qualified Person Responsible for Pharmacovigilance should be notified immediately | **ADE**  **Quality Defect**  **None** |
| **Preliminary Quality Defect Classification** | **Class 1  Class 2  Class 3**  **No Quality Defect** |
| **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** | |
| **Complaint founded** | **Complaint unfounded** |
| **Indicate the reason if the Complaint is unfounded:** | |

|  |  |
| --- | --- |
| **Preliminary Action Plan** | |
| **Internal investigation initiation** | **YES  NO** |
| **Product shipment Return** | **YES  NO  Not justified** |
| **Product Recall** | **YES  NO  Not justified** |
| **Segregation/Quarantining measures** | **YES  NO  Not justified** |
| **Competent authorities notification** | **YES  NO  Not justified** |
| **Comments** |  |
| **Justified by:** | **Date/Signature** |
| **Approved by {{ QualityOrganizationHead }}:** | **Date/Signature** |