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| **{{ 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:** |

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| **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** |