|  |  |
| --- | --- |
| **{{ ComplaintPrelimAssess }}** | |
| **CRN** |  |
| **Notification Date** |  |
| **Complaint Category** | **Product related (e.g. ADE, Quality Defect)**  **Distribution operation** |
| **Supposed Reasons**  **(Only for Distribution operations Complaints)** | |
| **Delay  Mix-up  Quantity  Packaging  Labeling  Damage  Contamination  Falsified products  Transportation conditions  Data/documents processing  Safety/Security  N/A** | |
| **Complaint founded**  **Complaint unfounded** | **Product related Complaint** |
| **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** |
| **Manufacturer/ MAH /Importer/ Supplier/ Customer/ Provider notification** | **YES  NO  Not justified** |
| **Comments** |  |
| **Justified by:** | **Date/Signature** |
| **Approved by {{ QualityOrganizationHead }}:** | **Date/Signature** |