|  |
| --- |
| **{{ 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** |