**Complaint Investigation Report**

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| **Product details** |
| **CRN** |  |
| **Notification Date** |  |
| **Name of drug product** |  |
| **Strength of drug product** |  |
| **Lot/Batch number** |  |
| **Manufacturing date** |  |
| **Expiry date** |  |
| **Product packaging details** |  |
| **Description of Complaint** |  |
| **Final Quality Defect Classification** | [ ]  **Class 1** [ ]  **Class 2** [ ]  **Class 3** |

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| **Scope of investigation** |
| **Departments/functions/processes** |

| **Complaint samples details** |
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| **Available number of samples and their condition** |  |
| **Physical inspection of complaint sample results** |  |
| **Available number of reference and retention samples (lot/batch, quantity)** |  |
| **Tests performed on complaint samples** |  |
| **Analytical results of complaint samples** |  |
| **Tests performed on the reference samples** |  |
| **Analytical results of the reference sample** |  |
| **Comparison results complaint samples with retention samples** |  |
| **Review of stability data** |  |

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| **Documents and records were reviewed for investigation purposes** |
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| **Risk Assessment Summary** |
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| **Root Cause Analysis Summary** |
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| **Impact on particular batch / Other batches of the same product / Other products** |
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| **Overall product segregation measures** |
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| **Proposed CAPAs** |
| **Reference CAPA number** | **Description** |
| **Reference CAPA number** | **Description** |

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| **Final disposition decision (recall, release, return)** |
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| **Complaint Investigation Report Conclusion and proposals** |
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| **Complaint Investigation Report prepared by:** (to be signed off by all involved SMEs) |
| Investigator | Name/Date/Signature |
| Investigator | Name/Date/Signature |
| Investigator | Name/Date/Signature |

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| **Complaint Investigation Report reviewed by:** |
| Department Head or Team Lead | Name/Date/Signature |
| Department Head or Team Lead | Name/Date/Signature |
| Department Head or Team Lead | Name/Date/Signature |

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| **Complaint Investigation Report approved by:** |
| Quality Management Director | Name/Date/Signature |