

**S INFORMATION**

**ION INFORMATION ON DRUG SUBSTANCE AND DRUG P**

**Section 2: PRODUCT RODUCT**

**LOTS**

**Section 1: FACILITIE**

- Address and a brief description of responsibility for each facility should be provided.

**1.1. Drug substance**

**1.2. Drug product**

**2.1 Drug product lots sold during Reporting period**

**Section 2: PRODUCTION INFORMATION ON DRUG SUBSTANCE AND DRUG PRODUCT LOTS**

**Section 1: FACILITIES INFORMATION**

**Yearly biologic product report (YBPR) Check list**

|  |  |
| --- | --- |
| **Product name/Type** |  |
| **Manufacturer** |  |
| **Reporting period** |  |
| **Contact information for this YBPR** |  |

|  |  |  |
| --- | --- | --- |
| **Facility** | **Address** | **Responsibility / Product type** |
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| --- | --- | --- |
| **Facility** | **Address** | **Responsibility / Product type** |
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| --- | --- | --- | --- | --- |
| **Drug Identification Number (DIN)** | **Dosage form** | **Strength** | **Number of lots sold** | **Release market** |



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# Lot disposition

* Number of aborted, rejected and released lots should be provided for each manufacturing facility separately with a brief discussion about each lot.

## Drug substance



|  |  |  |
| --- | --- | --- |
| **Facility name / Product type** | **Current reporting period** | **Previous reporting period** |
| **Aborted** | **Completed** | **Aborted** | **Completed** |
| **Quarantined** | **Rejected** | **Released** | **Quarantined** | **Rejected** | **Released** |
|  |  |  |  |  |  |  |  |  |
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-Detailed clarification on the cases of aborted, quarantined and rejected lots:

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## 2.2.2. Drug product

|  |  |  |
| --- | --- | --- |
| **Facility name / Product type** | **Current reporting period** | **Previous reporting period** |
| **Aborted** | **Completed** | **Aborted** | **Completed** |
| **Quarantined** | **Rejected** | **Released** | **Quarantined** | **Rejected** | **Released** |
|  |  |  |  |  |  |  |  |  |
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-Detailed clarification on the cases of aborted, quarantined and rejected lots:

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# Reprocessed lots

* List of lots subjected to reprocessing should be provided for each manufacturing facility separately.
* For each affected lot provide lot number, facility name, product type, reason for reprocessing, overview of reprocessing steps, regulatory status and whether lot sold

## Drug substance

*Facility name:………………..*

*Product type:…………………*

**2.3.2. Drug product**

*Facility name:………………..*

*Product type:…………………*

# Reworked lots

* List of lots subjected to reworking should be provided for each manufacturing facility separately.
* For each affected lot provide lot number, facility name, product type, reason for reworking, overview of reworking steps, regulatory status and whether lot sold

## Drug substance

*Facility name:………………..*

*Product type:…………………*

## 2.4.2. Drug product

*Facility name:………………..*

*Product type:…………………*

# Critical deviations and non-conformances

* List of Critical deviations and non-conformances should be provided for each manufacturing facility separately.
* For each event provide an overview of associated investigations with root cause analysis, resolution with corrective and preventative actions and resulting product lot disposition.

## Drug substance

*Facility name:…………………*

*Product type:………………….*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description of event** | **Date investigation initiated** | **Root cause** | **Resolution and corrective and preventativeaction (CAPA)** | **Product disposition** |
|  |  |  |  |  |
|  |  |  |  |  |

## 2.5.2. Drug product

*Facility name:…………………*

*Product type:………………….*

**3.1 Invalid lot release tests**

\* List of associated test method and for each test method data on total number of performed tests, number and percentages of invalid tests with summery of causes resulting in invalid tests should be provided for each testing facility separately.

*Facility name:…………………*

*Product type:………………….*

**3.2 Retesting due to out-of-specification (OOS) test results**

\* List of associated test method and for each test method provide the total number of tests performed, the number of tests resulting in an out-of-specification (OOS) test result, number of OOS results confirmed by retesting, and a summary of causes resulting in unconfirmed (false) OOS test results, including the associated corrective and preventative actions.

**Section 3: INFORMATION ON ANALYTICAL METHOD PERFORMANCE**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description of event** | **Date investigation initiated** | **Root cause** | **Resolution and corrective and preventative action (CAPA)** | **Product disposition** |
|  |  |  |  |  |
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|  |  |  |
| --- | --- | --- |
| **Test name** | **Current reporting period** | **Previous reporting period** |
| **Total number of tests performed** | **Percentage of invalid tests** | **Explanation/cause and any corrective/preventive actions** | **Total number of tests performed** | **Percentage of invalid tests** |
|  |  |  |  |  |
|  |  |  |  |
|  |  |

*Facility name:…………………*

*Product type:………………….*

|  |  |  |
| --- | --- | --- |
| **Test name** | **Current reporting period** | **Previous reporting period** |
| **Total number of tests performed** | **Number of OOS** | **Number of confirmed OOS** | **Details** | **Total number of tests performed** | **Number of OOS** | **Number of confirmed OOS** |
|  |  |  |  |  |  |  |  |
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| --- | --- | --- | --- |
| **Brief description** | **Rationale** | **Change level** | **Regulatory status** |
|  |  |  |  |
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|  |  |  |  |
| --- | --- | --- | --- |
| **Brief description** | **Rationale** | **Change level** | **Regulatory status** |
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## Drug substance

\* For each manufacturing facility, provide a separate list of changes implemented during the reporting period that have a potential impact on product quality

**Manufacturing process and controls**

**Drug substance**

*Facility name:…………………*

*Product type:………………….*

**4.1.2 Drug product**

*Facility name:…………………*

*Product type:………………….*

**4.2**

**Raw material suppliers and non-compendial specifications**

**Section 4: SUMMARY OF CHANGES**:

*Facility name:…………………*

*Product type:………………….*

|  |  |  |  |
| --- | --- | --- | --- |
| **Brief description** | **Rationale** | **Change level** | **Regulatory status** |
|  |  |  |  |
|  |  |  |  |

## Drug product

|  |  |  |  |
| --- | --- | --- | --- |
| **Brief description** | **Rationale** | **Change level** | **Regulatory status** |
|  |  |  |  |
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| --- | --- | --- | --- |
| **Brief description** | **Rationale** | **Change level** | **Regulatory status** |
|  |  |  |  |
|  |  |  |  |

*Facility name:…………………*

*Facility name:…………………*

*Product type:………………….*

**4.3 Analytical methods**

*Facility name:…………………*

*Product type:………………….*

For each manufacturing facility a separate list of lot release tests and for each test provide associated acceptance criteria, the range of result values, and identify any overall shifts or trends.

For each test provide in the Appendix control charts (indicating acceptance limits, mean, and standard

deviation) representing all lots manufactured during the current reporting period.

If trend or shift is detected, provide in the Appendix tabulated summary of the data, including the status of relevant investigations.

**5.1 Drug substance**

**Section 5: LOT RELEASE TEST RESULTS**

*Product type:………………….*

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| --- | --- | --- | --- |
| **Lot release test** | **Acceptance criteria** | **Range of results (n)** | **Observed shifts or trends** |
|  |  |  |  |
|  |  |  |  |

**5.2.2 Drug product**

*Facility name:…………………*

*Product type:………………….*

**Section 7: PRODUCT RECALL AND CORRECTIVE ACTIONS**

**Section 6: ANALYSIS OF ADVERSE DRUG REACTION REPORTS ATTRIBUTABLE TO PRODUCT QUALITY**

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| --- | --- | --- | --- |
| **Lot release test** | **Acceptance criteria** | **Range of results (n)** | **Observed shifts or trends** |
|  |  |  |  |
|  |  |  |  |