Name of the Intermediate / Salable Intermediates / API Products:

Batch Number :

Mfg. Date :

Analytical Report No. :

Analytical Report No created on :

Batch Quantity :

**No. of Containers (N) :**

|  |
| --- |
| **Calibration of Movable Balance: Balance ID No.:**  Observed Weight of 10g standard weight: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_g (Passed/Failed)  (Allowed range between 9.80-10.20g)  Performed by:  (Sign&Date) |

**A. Sample Quantity determination:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S.No.** | **Purpose of Sample** | **Quantity required**  **[g (or) mL]** | **Reference Document No.**  **(STP / Protocol)** | **Remarks** |
| 1 | Release testing &  Reserve sample |  |  |  |
| 2 | Stability Study |  |  |  |
| 3 | Hold time study |  |  |  |
| 4 | Any other Specify  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

**Approx. total sample quantity required (W) : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ g (or) mL**

Samples to be collected from all individual containers for composite sample preparation.

Minimum Quantity to be taken from individual container for composite sample preparation. Sample

Quantity to be collected by using following formula;

Total Sample Qty

= -------------------------------- = --------------------------------- =

No. of Containers (N)

**Sampled by (Name) :**

**Sign & Date :**

**B.** **Sampling Checklist**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S.No** | **Description of Inspection** | **Yes** | **No** | **NA** | **Remarks** |
|  | Are the details verified in the sample request |  |  |  |  |
|  | Is the appropriate sampler chosen, clean, dry and covered properly? |  |  |  |  |
|  | Does the sampler have all the components? Is the bottom screw portion of the sampler properly tightened? |  |  |  |  |
|  | Does the container label have all detailed  information? |  |  |  |  |
|  | Is the sampling area clean? |  |  |  |  |
|  | Ensure that only one batch material is sampled at a time? |  |  |  |  |
|  | Is the physical condition of the container good? |  |  |  |  |
|  | Are sampled containers properly labeled? |  |  |  |  |
|  | Are sample bags/containers appropriately labeled? |  |  |  |  |
|  | Are there any missing components of the sampling tool / aid after collection of sample? |  |  |  |  |
|  | After sampling all containers inner primary bags fastened with pilfer proof seals. |  |  |  |  |
|  | After sampling, ensure complete disposal of fasteners which are tagged to the bags/containers? |  |  |  |  |
|  | Is the sampling tool/aid cleaned, after completion of the sampling? |  |  |  |  |
|  | **Any other observations:** |  |  |  |  |

**Note: Put ‘√’ mark in the relevant box.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Container number | Inner bag sealed with white strap | Outer bag Seal number | Container number | Inner bag sealed with white strap | Outer bag Seal number |
|  | Yes / No |  |  | Yes / No |  |
|  | Yes / No |  |  | Yes / No |  |
|  | Yes / No |  |  | Yes / No |  |
|  | Yes / No |  |  | Yes / No |  |
|  | Yes / No |  |  | Yes / No |  |
|  | Yes / No |  |  | Yes / No |  |
|  | Yes / No |  |  | Yes / No |  |
|  | Yes / No |  |  | Yes / No |  |
|  | Yes / No |  |  | Yes / No |  |
|  | Yes / No |  |  | Yes / No |  |

Note: Attach separate sheet, if the sampling containers are more.

|  |  |  |
| --- | --- | --- |
| All containers are sealed properly and intact | | Yes / No |
| Sampled & Sealed by  (QC) &Date: |  | |

**C. Sample Collection:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Container**  **No.** | **Sampled**  **Qty**  **g (or) mL** | **Container is**  **intact and is in good condition** | | **Sampled container**  **properly sealed**  **after sampling** | | **Sampled container**  **properly labelled**  **after sampling** | | **Remarks** |
| **Yes** | **No** | **Yes** | **No** | **Yes** | **No** |
|  |  |  |  |  |  |  |  |  |
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| **Container**  **No.** | **Sampled**  **Qty**  **g (or) mL** | **Container is**  **intact and is in good condition** | | **Sampled container**  **properly sealed**  **after sampling** | | **Sampled container**  **properly labelled**  **after sampling** | | **Remarks** |
| **Yes** | **No** | **Yes** | **No** | **Yes** | **No** |
|  |  |  |  |  |  |  |  |  |
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Note: Attach separate sheet, if the sampling containers are more. Put ‘√’ mark in the relevant box.

**No. of Containers sampled: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Total Sampled Qty [g(or)mL] : \_\_\_\_\_\_\_\_\_\_\_\_**

Sampled By: Checked By (Head QCD/Designee):

Sign & Date: Sign & Date:

**D. Sample Distribution: Balance ID No.:**

The Composite sample is distributed in Quality control Laboratory as follows:

|  |  |  |
| --- | --- | --- |
| **S. No.** | **Distribution of QC samples** | **Quantity [g (or) mL]** |
| 1 | Reserve sample |  |
| 2 | Chemical analysis |  |
| 3 | Instrumental analysis |  |
| 4 | Physical tests |  |
| 5 | Any other Specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| 6 | Left over quantity after distribution (x) |  |

**Distributed By:**

**(Sign & Date)**

|  |  |  |
| --- | --- | --- |
| **S.No.** | **Distribution of QC samples** | **Quantity [g (or) mL]** |
| 7 | Total left-over quantity from S.No.1 to 5 after analysis (y) |  |
| 8 | Total quantity of leftover sample disposed off (x+y) |  |

**Disposed By: Checked By:**

**Sign & Date: Sign & Date:**

**Note:** 1. Write “NA” whichever Not Applicable.

2. QCD personnel shall collect and send the total leftover sample before and after analysis upon

completion of all tests for disposal as per the respective disposal procedure.