



DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: Operation, Cleaning and Maintenance of Sampling Device

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

- 1. Purpose:** To define the procedure for operation, cleaning and maintenance of the sampling rods (sampler), and withdrawal of samples as per sampling points.
- 2. Scope:** This procedure is applicable to following sampling rods and dies utilized for sampling in-process materials at drying and blending stages of granulation.

Equipment	Purpose
Unit dose Sampling rod	To collect samples for test of blend uniformity.

3. References, Attachments & Annexures:

3.1 References:

- 3.1.1 SOP on "Identification and Status Labelling Procedure" SOP.
- 3.1.2 SOP on "Cleaning of newly received SS parts, SS Fabricated Parts of Equipments".

3.2 Attachments:

- 3.2.1 Attachment-1: Cleaning and uses log for sampling rod and Die.
- 3.2.2 Attachment-2: Sampling Die Inspection Record.
- 3.2.3 Attachment-3: Sampling Die Disposal Record.

3.3 Annexures: NA

4. Responsibilities:

4.1 Quality Assurance Department :

- 4.1.1 Operation of the equipment.
- 4.1.2 Ensuring simultaneous entries in the sequential log of respective equipment.
- 4.1.3 Withdrawal of sample as per sampling points.
- 4.1.4 To ensure the Cleaning of sampling rods and its record.

4.2 Head Quality Assurance:

- 4.2.1 To ensure training and implementation of the SOP.

4.3 Regulatory Affairs, Quality Head & Plant Head:

- 4.3.1 To review and approve the SOP.

5. Distribution:

- 5.1 Quality Assurance

6. Abbreviations & Definitions of Terms:

6.1 Abbreviations:

- 6.1.1 **SOP** : Standard Operating Procedure
- 6.1.2 **QC** : Quality Control
- 6.1.3 **QA** : Quality Assurance



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Department: Quality Assurance	SOP No.:
Title: Operation, Cleaning and Maintenance of Sampling Device	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

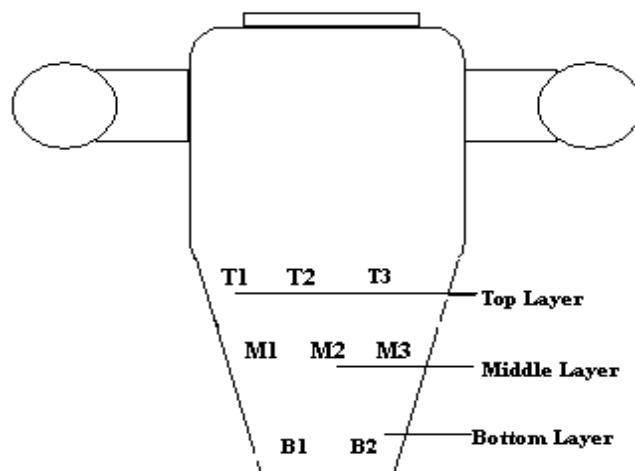
6.2 Definitions of Terms: NA

7. Procedure:

7.1 Cleaning procedure for Sampling Rod and Die:

- 7.1.1 After use of sampling rod and Die. Rinse using potable water for cleaning and re cleaned by purified water.
- 7.1.2 Check the cleanness visually, if any adhered material, dirty spot found repeat the process.
 - 1.1.1 Collect wash water sample and send it to QC for analysis.
- 7.1.3 After getting approval from QC ensure CLEANED status label and its validity before using the sampling rod.
- 7.1.4 Ensure the cleanliness of sampling rod and its parts visually before its usage.
- 7.1.5 Maintained the cleaning and uses log as per Attachment - 1
- 7.2 Different dies are available for sampling rod according to its fill capacity.
- 7.3 Determine suitable die by filling the chamber with the blend taking care not to disturb the sampling points to ascertain the sample weight.
 - 7.3.1 **For Unit Dose Sampling Rod with replaceable dies:**
 - 7.3.1.1 Blend sample shall be collected from bunker as per respective protocol utilizing sampling rod.
 - 7.3.1.2 Place the required die in the sampling rod.
 - 7.3.1.3 Insert the sampling rod into the blend to be sampled taking care that the die is in closed condition.
 - 7.3.1.4 The schematic diagram of sampling location of blend from side view of blender as illustrated in figure-1.

Figure-1





DECODING PHARMA

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STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Operation, Cleaning and Maintenance of Sampling Device	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

7.3.1.5 Open the sampling rod and move the rod little in horizontal direction across the blend to ensure proper filling up of the chamber and close the sampling rod.

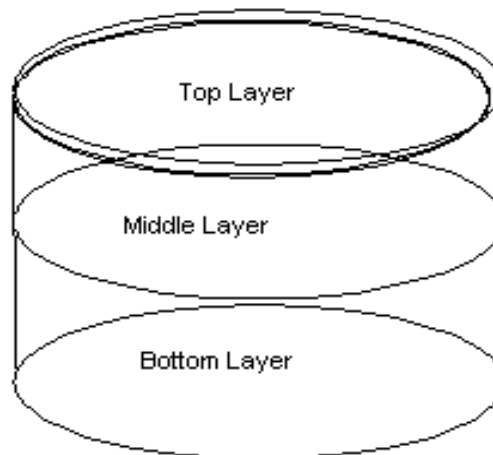
7.3.1.6 Remove the sampling rod from the blend and open it to empty the sample into a pre-labeled poly bags, Black poly bag shall be used for define sampling procedure in triplicate, covering the entire sampling points. The number of sample may vary based on any specific instruction mentioned in sampling protocol.

7.3.2 Sample collection for physical parameters.

7.3.2.1 Sample shall be collect for physical parameter checks.

7.3.2.2 The schematic diagram of the sampling location of blend in drum as illustrated in figure-2.

Figure-2



7.3.2.3 Collect samples from Top, Middle and Bottom Layer during unloading of bulk as mentioned in the sampling diagram of Figure-2, as per the sampling protocol.

7.4 Procedure for verification and approval of newly received sampling die

7.4.1 Verify the die for order, supplier, suitability to sampling rod.

7.4.2 Verify MOC certificate of die.

7.4.3 Physically verify the die for burrs, dents, scratches, finish etc.

7.4.4 Perform the Passivation test of sampling die as per SOP of newly received S.S parts SOP.

7.4.5 Take dimension with Vernier caliper of sampling die to match with sampling rod and record in Attachment 2.

7.4.6 Verify the die cavity by adding water up to the cavity level and check for capacity of sampling die and record in attachment 2.



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Department: Quality Assurance	SOP No.:
Title: Operation, Cleaning and Maintenance of Sampling Device	Effective Date:
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Issue Date:	Page No.:

- 7.4.7 Give the number of die. For first die number should be 1/3 i.e 1 indicates die number and 3 indicates total number of dies available.
- 7.4.8 Take approval from quality assurance head and quality head.
- 7.5 **Procedure for rejection and disposal of sampling die:**
- 7.5.1 If any newly received die fails in inspection then return it to the party.
- 7.5.2 If any sampling die damaged during handling than reject it.
- 7.5.3 If any sampling die do not fit in to rod then reject it.
- 7.5.4 If any sampling die do not match with it's capacity then reject the die.
- 7.5.5 For disposal of sampling die give it to the maintenance department.
- 7.5.6 Take authorization of disposal of sampling die as per attachment 3.
- 7.5.7 The Maintenance department shall dispose the dies by damaging through grinding machine after making the entry in Sampling Die Disposal Record (Attachment 3) and then return the Record to the QA department.
- 7.6 All existing drum shall be inspected in a year.



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STANDARD OPERATING PROCEDURE

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Issue Date:

Page No.:

Attachment – 2 Sampling Die inspection Record

Sampling Die No.	Date of Receipt	Capacity in CC	Dimension		Volume of water added by calibrated pipette	Observation (For overflow)	Remarks
			Length	Breadth			

Checked By:	Verified By:	Approved By:
Sign & Date	Sign & Date	Sign & Date



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Issue Date:	Page No.:

Attachment – 3 Sampling Die Disposal Record

Date:

Sampling Die No.:

Sampling Die capacity (in CC):

Reason for rejection:

Method of Disposal:

Die Disposed on:

Sign/Date

Checked By:	Verified By:	Approved By:
Sign & Date	Sign & Date	Sign & Date



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Page No.:

8. History:

Version No.	Effective Date
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