DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Sampling of Intermediates and Finished Products	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for sampling of intermediates and finished product dosage form.

2.0 SCOPE:

This SOP is applicable to the sampling of the intermediates and finished product samples for in-process checks and final analysis of the product.

3.0 RESPONSIBILITY:

Production Officer and Quality Assurance officer.

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1. On receipt of ‘’intimation for testing ‘’ slip (Refer Annexure-I) from production, QA shall check that BMR is completed up to that stage.

5.2 QA shall prepare a ‘’sample for analysis’’ label as per Annexure-II.

5.3 Affix the label on the clean container to be used for sampling i.e. clean bottle or clean polybag.

5.4 Ensure that sampling thief (if required) or that the sampling tools such as stainless steel spoons and spatulas are cleaned before use.

5.5 Wear the latex hand gloves and mask.

5.6 Ensure that in-process container is affixed with label of correct product / batch number and batch details.

5.7 Open the in-process containers and withdraw approximately equal quantity of sample from each of the containers and collect in the clean polybags or bottles by using the cleaned sampling devices as per sampling plan given below:

S.No.	Stage	Sampling plan
1.	Blend/Granules	Approximately 50 ml/50 g or as defined in standardization or validation protocol
2.	Core or Coated Tablets/ Filled hard gelatin or soft gelatin Capsules	Approximately 50 tablets/ Capsules or as defined in standardization or validation protocol or as per finished product specification or lot wise wherever required.
3.	Finished Product (Tablets/Capsules)	As per finished product specification
4.	Cleaning Validation Sample	As per Validation

5.8 Composite sample shall be prepared from the individual samples drawn from each container by mixing homogeneously equal portions in a polybag from individual samples.

5.9 In case of finished product, sample shall be collected form each individual container to make a pool samples, quantity sufficient as specified in finished product specification.

5.10 Close the in process containers immediately.

5.11 Send the samples with ‘intimation for testing’ slip to Quality Control for analysis.

5.12 In case of Cleaning Validation, sample shall be collected form each individual container quantity sufficient as specified in specification.

6.0 ABBREVIATION(S):

BMR : Batch Manufacturing Record

QA : Quality Assurance

QC : Quality Control

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure-I : 'Intimation for Testing' slip

Annexure-II: 'Sample for analysis' label

Annexure-II: Intimation for Cleaning Sample' slip

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION