DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Sampling procedure for withdrawal of Stability Samples	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1. **Purpose:** This Standard Operating Procedure defines the procedure for withdrawal of Stability samples.

2. **Scope:** This procedure is applicable for collection of stability samples for all drug products manufactured at …….

3. **Reference, Attachments & Annexure:**
   3.1. **Reference:**
   3.1.1. In House

   3.2. **Attachments:**
   3.2.1. Attachment – 1 Stability Sampling register
   3.2.2. Attachment – 2 Stability Test Request Form

   3.3. **Annexure:** NA

4. **Responsibility:**
   4.1. **Quality Assurance:**
   4.1.1. To inform QC regarding type of stability study to be performed.
   4.1.2. To withdraw samples as per defined procedure.
   4.1.3. To send the stability samples to QC for stability study and maintain the stability sampling register.
   4.1.4. To send duly filled Stability Test Request Form to Quality Control (QC).
   4.1.5. To maintain withdrawal record of stability sample in stability sampling register.

   4.2 . **Quality Control:**
   4.2.1 To receive the stability samples as per required condition through Stability Test Request Form.
   4.2.2 To calculate the sample quantity and to inform QA about sample quantity.

5. **Distribution:**
   5.1. Quality Assurance
   5.2. Quality Control

6. **Abbreviations and Definition of Terms:**
   6.1. **Abbreviations :**
   6.1.1. ACC - Accelerated Condition
   6.1.2. LTC - Long term Condition
   6.2. **Definition of Terms:** NA

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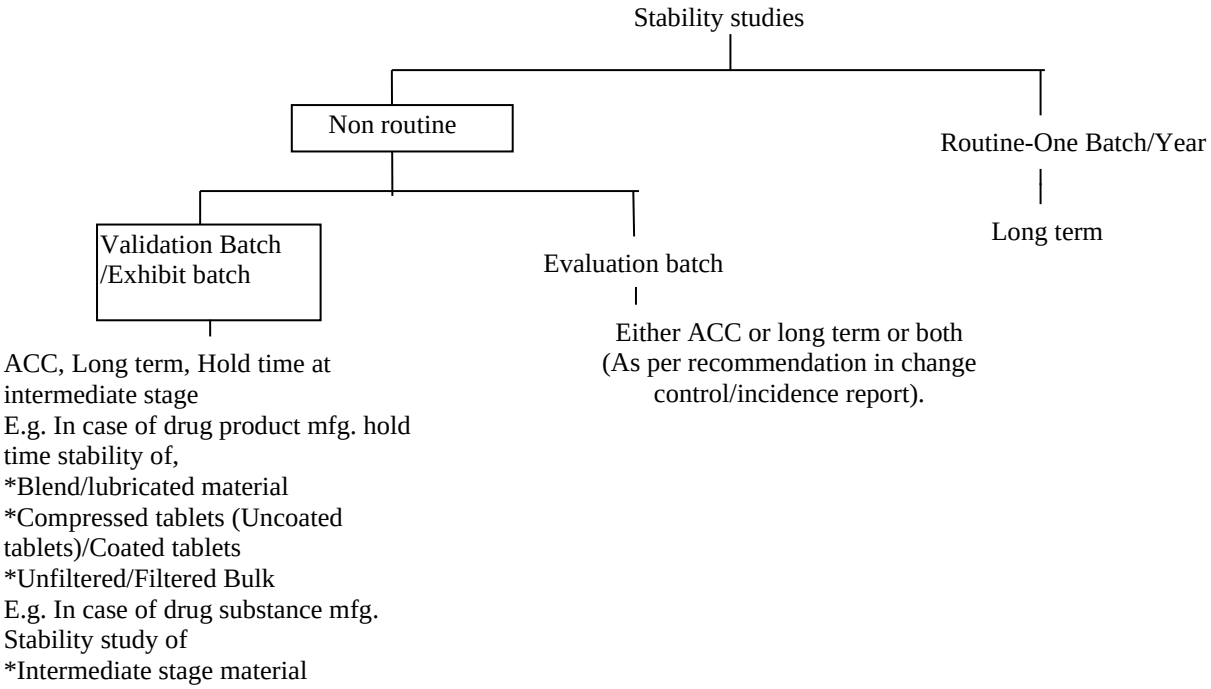
7. Procedure:

7.1.Criteria for deciding type of stability study to be performed:



7.1.1. Routine stability study:

7.1.1.1. In case of routine stability, samples of one batch per product per year shall be kept for long-term stability study.

7.1.2. Non routine stability study:

Following are the examples of non-routine stability study.

7.1.2.1. In case of new product after successful scale-up (i.e. only qty. adjustment or process adjustment is permitted during scale-up), samples of three consecutive batches/validation batches shall be kept for ACC & long-term stability.

7.1.2.2. In case of drug product manufacturing; hold time/stability study at intermediate stage shall be performed while manufacturing of exhibit batch or process validation batch.

E.g. Hold time study of,

* Blend/lubricated material.
* Compressed tablets (Uncoated tablets)/Coated tablets.

7.1.2.3. In case of drug substance manufacturing; hold time/stability study of intermediate stage material shall be performed.

7.1.2.4. Three consecutive batches means: Three batches of a product X manufactured can have batch numbers X-001, X-005 & X-007, where, in-between batch numbers can be of any other product.

7.1.2.5. Stability studies shall be performed on each individual strength and container/pack size of the drug product unless bracketing or matrixing is applied. i.e. If the product is

packed in three different size (100 count, 500 count & 1000 count) of container/bottle/jar, stability study for all three pack size shall be done.

7.1.2.6. Stability study of evaluation batch means, recovery added batch, reprocessed batch, recommendation in temporary or permanent change control or incidence report etc.

7.1.2.7. In case if the scale up is not successful or major changes done, 3M ACC or ACC & CRT stability or stability study as per recommendation in temporary or permanent change shall be done.

7.1.2.8. Photostability studies shall be done as per regulatory requirement of respective country and/or labeling statement.

7.2. **Sampling for stability studies:**

7.2.1. QA shall inform QC regarding type of stability study to be performed.

7.2.2. QC shall calculate the sample quantity and shall inform to QA.

7.2.3. Total sample quantity per batch shall be 1.25 times the quantity required for single complete or partial analysis & based on number of stability stations plus additional one station (since stability testing has to be continued for 12 month beyond the expiry).

7.2.4. In case of drug products (formulation), QA shall withdraw random samples through out packaging of the batch (to have representative samples of the entire batch) after verifying according to in process checks & FP results within limit & in the final pack so as to simulate the market pack.

7.2.5. After withdrawal of the samples, QA shall enter the details like, sr. no., product name, batch no., date of sample withdrawal in stability (routine & non routine) sampling register (Attachment – 1).

7.2.6. QA shall mention quantity of sample, sampled by, date & purpose in batch packing record (BPR).

7.2.7. QA shall enter the details like, Product, Request No., Release date (QC), Batch no., Manufacturing date, Expiry date, BMR & BPR record no., MBMR No., AR no of used API(s), Storage condition, Purpose, Status, Pack size, Packing date, Sampled by and Sample quantity in the “Stability Test Request Form” (Attachment – 2) & send samples to QC.

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Attachment – 1
Stability Sampling Register

STABILITY SAMPLING REGISTER (Routine & Non Routine) – Year _____

S.No.	Product	Batch No.	Mfg Date	Exp. Date	Date of Sampling	Total Qty withdrawal	Reason for Stability	Sampled by	Received by	Remarks

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Attachment – 2
Stability Test Request Form

From	Quality Assurance	Request No.:	STR/ /
To	Quality Control	Date:	

Product		Batch Size:		
Batch No.		Average		
Mfg. Date		Exp. Date:		
BMR		BPR Record		
MBMR		Packing Date		
Pack Size		Release Date:		
Used API AR No.	1	2	3	
	4	5	6	
	7	8	9	
Type/Purpose of stability	Existing Product (Routine) [ ]			
				Validation [ ]
		New product [ ]		Permanent Change control [ ]
		Stability/Exhibit [ ]		Temporary Change [ ]
		Incidence [ ]		Others.....
				Details:
Storage	ACC + LTC	ACC [ ]	LTC [ ]	
Batch	I Batch [ ]	II Batch [ ]	III Batch [ ]	
Dosage				
Primary Packing Material	Alu – Alu Strip [ ]	Alu – PVC Blister [ ]		Alu – PVDC Blister [ ]
		Alu – Alu Blister [ ]	Alu – PVC-PVDC [ ]	Sachet [ ]
		Bottle [ ]		
				Others.....
Sampled By/Date				
Sample Qty.				
Sample Received By/Date (QC)				
Remarks				

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8. **History**

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