STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: In Process and Finished Product Sampling	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 PURPOSE

To define a procedure for in-process and finished product sampling during manufacturing and packing operations.

2.0 SCOPE

2.1 This procedure applies to in process and finished product sampling, analysis and reporting to be carried out during manufacturing and packing operations in ……..

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 In-house

3.2 Attachments

3.2.1 Attachment- I : Test request form (TRF)

3.2.2 Attachment- II : In process/Finished Product Sampling log

3.2.3 Attachment- III : Sample Quantity of Uncoated/ Coated Tablet for Analysis

3.2.4 Attachment- IV : Sample Quantity of Filled Capsule for Analysis

3.2.5 Attachment- V : Sample Quantity for Stability Study

3.2.6 Attachment- VI : Control Sample Quantity of Finished Product (Sale pack)

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 Nil

4.2 Abbreviations

4.2.1 QA : Quality Assurance

4.2.2 QC : Quality Control

4.2.3 SOP : Standard Operating Procedures

4.2.4 BMR : Batch Manufacturing record

4.2.5 g : Gram

4.2.6 BPR : Batch Packing Record

4.2.7 IPQA : In-process Quality Assurance

4.2.8 Qty. : Quantity

4.2.9 No : Number

4.2.10 A.R. No. : Analytical Reference Number

4.2.11 Sr. No. : Serial Number

4.2.12 Mfg. Dt.: Manufacturing Date

4.2.13 Exp. Dt.: Expiry Date

4.2.14 IPC: In-process container

4.2.15 Qty.: Quantity

4.2.16 Approx.: Approximately

5.0 RESPONSIBILITY:

5.1 Production:

5.1.1 To raise Test request form (TRF) as per SOP.

5.2 Quality Control:

5.2.1 To prepare the product wise sample quantity details required for analysis purpose for blend, uncoated tablet, coated tablet, filled capsule, stability study.

5.2.2 To receive and analyze the sample submitted by Quality Assurance.

5.2.3 To report the result of analysis of the sample to Quality Assurance.

5.2.4 To prepare the product wise sample quantity details required for finished product control sample (sale/ physician) and for stability study.

5.3 Quality Control Head:

5.3.1 To check the product wise sample quantity details required for analysis purpose for blend, uncoated tablet, coated tablet, filled capsule, stability study and finished product control sample (sale/ physician) prepared by Quality Control person.

5.4 Quality Assurance:

5.4.1 To sample in-process material and finished product as per request and/ or sampling plan.

5.5 Quality Assurance Head:

5.5.1 To approve product wise sample quantity details required for analysis purpose of blend, uncoated tablet, coated tablet, filled capsule, stability study and finished product control sample (sale/ physician).

5.5.2 To ensure implementation of the defined procedure.

5.6 Plant Head:

5.6.1 To ensure implementation of the defined procedure.

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: In Process and Finished Product Sampling	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

6.0 Distribution:

I. Quality Assurance

II. Quality Control

III. Production

7.0 PROCEDURE:

7.1 After completion of in-process / finished product stage, Executive/Officer – Production shall fill the details in Test Request Form as per **Attachment-I** and intimate to Officer/Executive - IPQA for sampling.

7.2 The Test Request Form **(Attachment-I)** shall be used as perforated log in triplicate (white, pink and green).

- Ist Copy (white) for record purpose in Quality Control department.
- IInd Copy (Pink) shall be attached with respective BMR.
- IIIrd Copy (Green) retained with perforated log.

7.3 Upon receipt of intimation, Officer/Executive - Quality Assurance shall carryout sampling after confirming following points:

7.3.1 The Batch Manufacturing Record (BMR)/ Batch Packing Record (BPR) is complete up to that stage and all the manufacturing steps were followed and documented, including stage wise yields.

7.3.2 All the containers have affixed labels with correct product and batch details.

7.3.3 Sampling Tools, fresh self-sealing polybags and labels (Sample for analysis, Sampled and Under Test) are available.

7.4 In-Process Sampling:

7.4.1 **Sampling of blend (After lubrication) sample:**

7.4.1.1 Collect the samples into self-sealing polybag from at least three different locations (top, middle and bottom of each container) by using a Sampling Tool (Cleaned Spatula/Sampling Rod) and make a homogeneous composite sample.

7.4.1.2 Composite sample quantity of blend shall be approximately 100 gm for a batch.

7.4.1.3 Properly tie the poly bags and containers after the sampling operation.

7.4.2 **Sampling of uncoated tablet**

7.4.2.1 Open the closer & cable tie of the polybags and collect the uncoated tablets into fresh self-sealing polybag randomly from each bin (HDPE) after completion of compression the batch.

7.4.2.2 Composite sample quantity of uncoated tablet shall be the quantity required as per current approved list of

"Composite Sample Quantity of Uncoated/ Coated Tablet" as per **Attachment-III**.

7.4.2.3 Properly tie the polybags and containers after the sampling operation.

7.4.3 **Sampling of coated tablet**

7.4.3.1 Open the closer & cable tie of the polybags and collect the coated tablets into fresh self sealing polybag randomly from each bin (HDPE) after completion of coating of the batch.

7.4.3.2 Composite sample quantity of coated tablet shall be the quantity required as per current approved list of "Composite Sample Quantity of Uncoated/ Coated Tablet" as per **Attachment-III**.

7.4.3.3 Properly tie the poly bags and containers after the sampling operation.

7.4.4 **Sampling of Filled Capsule**

7.4.4.1 Collect the filled capsules into fresh self-sealing polybag randomly from each bin (HDPE) after completion of AQL as per SOP titled "Acceptance Quality Level".

7.4.4.2 Composite sample quantity of filled capsule shall be the quantity required as per current approved list of "Composite Sample Quantity of Filled Capsule" as per **Attachment-IV.**

7.4.4.3 Properly tie the poly bags and containers after the sampling operation.

7.4.5 **Sampling of Microbiological Sample:**

7.4.5.1 Collect approx. 20 g of bulk finish sample (i.e. uncoated tablet, coated tablet, filled capsule) in fresh self-sealing polybag after completion of the processing.

7.4.5.2 Mention the qty. of microbiological sample collected in BMR and in the in-process and finished product log as per Attachment-II and submit the sample to QC along with the TRF raised by production department and the log.

7.4.6 After Sampling, Collected sample shall be kept into another fresh self-sealing polybag and affix the label of "Sample for Analysis" as per SOP titled "Status Labelling".

7.4.7 Officer/Executive - IPQA shall affix the "Sampled" and "Under Test" label on each container over "Under Process" label as per SOP titled "Status Labelling".

7.4.8 Sampled quantity shall be recorded in BMR.

7.4.9 Keep the sample poly bag in a sampling cage and fill the details into In-process/Finished product log as per **Attachment-II**. Officer/Executive - IPQA shall submit the sample to Quality Control department along with Test Request Form (White and Pink Copy) as per **(Attachment- I)** and log.

7.4.10 Concerned Officer/Executive-Quality Control shall receive the sample in log book.

7.4.11 Officer/Executive-Quality Control shall perform analysis as per SOP titled "Testing and release of In

process, Finished and Miscellaneous Samples".

7.4.12 Officer/Executive-Quality Control enter observations in Test Request/Report Form (white and pink copy) and send pink copy to Quality Assurance department and keep white copy for record purpose in Quality Control department.

7.4.13 Officer/Executive - IPQA shall review the results and send the report to Production department.

7.4.14 Officer/Executive - Production shall attach the report to the Respective BMR.

7.4.15 Officer/Executive Quality Assurance shall affix "Approved" label on each container over "Under Test" label as per SOP titled "Status Labelling".

7.5 Finished Product Sampling (QC Sample, Control Sample & Stability Sample)

7.5.1 During secondary packing operation, the sample of the product shall be collected at start, middle (every two hours) and end of operation.

7.5.2 Blisters shall be kept in their respective secondary packing in such a manner that they are identical to the final pack.

7.5.3 After completion of batch verify the sample quantity required as per Table No.-1, 2 or 3 and record in BPR.

7.5.4 **Collection of Finished Product sample for Quality Control Analysis**

7.5.4.1 The sample quantity of finished product for Quality Control Analysis shall be collected as per approved sample quantity prepared as per Attachment-III for tablets and Attachment-IV for Capsules.

7.5.4.2 Keep the sample in sampling cage and fill the details into In-process/Finished product log as per Attachment-II. Shrink wrap the sample and submit to Quality Control department along with Test Request Form (White and Pink Copy) and log.

7.5.4.3 Concerned Officer/ Executive- Quality Control shall receive the sample in log.

7.5.4.4 Officer/ Executive- Quality Control shall perform analysis as per SOP titled "Testing and release of In process, Finished and Miscellaneous Samples".

7.5.4.5 Officer/ Executive - Quality Control shall submit the Certificate of Analysis (COA) along with analytical data of the batch to Quality Assurance department.

7.5.5 **Collection of Control Sample**

7.5.5.1 **For Sale Pack**: The sample quantity of control sample for sale pack shall be equivalent to the quantity mentioned in Table No. - 2.

TABLE No. – 2

DOSAGE FORM	SAMPLE QUANTITY
Tablets/Capsules	Twice the quantity required for one complete analysis

7.5.5.2 **For Physician Sample Pack (PS)**: The sample quantity of control sample for Physician Sample Pack is equivalent to the quantity mentioned in Table No. - 2. In case of batch packed for sale as well as Physician sample, then sample quantity of control sample shall be equivalent to the quantity mentioned in Table No.- 3.

TABLE No. – 3

DOSAGE FORM	SAMPLE QUANTITY
Tablets/Capsules (PS)	Two full inner cartons in an outer carton (if outer carton is available) OR Two full cartons (if outer carton is not available)
Tablets/Capsules (Sale)	Twice the quantity required for one complete analysis

Refer Attachment- VI for sample quantity of finished product control sample (Sale Pack).

7.5.5.3 Intact blister shall be kept as control sample, even if quantity exceeds more than actual quantity required.

7.5.5.4 Keep the sample in sampling cage and fill the details into control sample log and follow the procedure for handling of control sample as per SOP titled “Handling of Control sample”.

7.5.6 **Collection of Sample for Stability Study**

7.5.6.1 Follow the procedure mentioned in the SOP titled “Stability Study” for collection of sample for stability study.

7.5.6.2 Collect the stability sample as per current approved list of “Sample Quantity for Stability Study” **Attachment-VII.**

7.5.7 **Sampling of Microbiological Sample**

7.5.7.1 During secondary packing operation, collect the no. of blisters equivalent to 20 g of sample (according to average weight of unit dosage) at start, middle (every two hours) and end of operation.

7.5.7.2 Mention the qty. of microbiological sample collected in in BPR and in the inprocess and finished product log Attachment-II and submit the sample to QC along with the TRF raised by production department and the log.

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: In Process and Finished Product Sampling	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

8.0 REVISION HISTORY

Version No.	00	Effective Date	
Details of revision: New SOP Prepared			

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: In Process and Finished Product Sampling	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment- I

TEST REQUEST FORM (TRF)

Block: _____

Product Name			
Product Code		**A.R. No.:**	
Batch No.		**Batch size**	
Stage		**Mfg. Date**	
Sampled Qty.		**Exp. Date**	
No. of containers sampled		**Total No. of containers**	
Tests to be performed (To Quality Control):			
Result after QC analysis: **As per QC Specification of the above sample:** ☐ **Complies** ☐ **Does not Complies**			

Initiated by:	Intimation received by:	Sampled by:	Sample received by:	Results Reported by:	Reviewed By	Received by:
Date &Time:	Date & Time:	Date & Time:	Date & Time:	Date & Time:	Date & Time:	Date & Time:
(Production/ QA)	(QA/ QC)	(QA/ QC)	(Quality Control)	(Quality Control)	QC Head/ Designee	(QA/ Production)

NOTE: Put '-' or 'NA' in the columns which are not required.
Put '√' wherever applicable.

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: In Process and Finished Product Sampling	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment- II

INPROCESS/FINISHED PRODUCT SAMPLING LOG

S.No.	Product Name	Batch No.	Mfg. Date	Exp. Date	Stage	Sample Qty. collected	Collected by QA Sign/ date	Sample received by QC Sign/ date	Remarks

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: In Process and Finished Product Sampling	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment- III

SAMPLE QUANTITY OF UNCOATED/COATED TABLET FOR ANALYSIS

S.No.	Product Name	Product Code	Stage	Sample Quantity for Analysis (In Nos.)
1.			Uncoated	
			Coated	
2.			Uncoated	
			Coated	
3.			Uncoated	
			Coated	

Prepared By QC (Sign/ Date)	Checked By QC Head (Sign/ Date)	Approved By QA Head (Sign/ Date)

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: In Process and Finished Product Sampling	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment- IV

SAMPLE QUANTITY OF FILLED CAPSULE FOR ANALYSIS

S.No.	Product Name	Product Code	Sample Quantity for Analysis (In Nos.)
1.			
2.			
3.			
4.			
5.			
6.			

Prepared By QC (Sign/ Date)	Checked By QC Head (Sign/ Date)	Approved By QA Head (Sign/ Date)

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: In Process and Finished Product Sampling	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Attachment- V

SAMPLE QUANTITY FOR STABILITY STUDY

S.No.	Product Name	Product Code	Sample Quantity (No. of Blisters/Strips/Inner Cartons/Outer Cartons/etc.)

Prepared By QC (Sign/ Date)	Checked By QC Head (Sign/ Date)	Approved By QA Head (Sign/ Date)

Attachment- VI

CONTROL SAMPLE QUANTITY OF FINISHED PRODUCT
(SALE PACK)

S.No.	Product Name	Product Code	Sample Quantity (No. of Blisters/Strips/Inner Cartons/Outer Cartons/etc.)
1.			
2.			
3.			
4.			
5.			
6.			
7.			

Prepared By QC (Sign/Date)	Checked By QC Head (Sign/Date)	Approved By QA Head (Sign/Date)