PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling and Verification of PM	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down procedure for Sampling and verification of the Packaging Material.

2.0 SCOPE:

This SOP is applicable to various Packaging Materials received.

3.0 RESPONSIBILITY - Execution - Executive QC

Checking - Assistant Manager QC

4.0 ACCOUNTABILITY - Manager Quality Control.

5.0 PROCEDURE:

5.1 Sampling Procedure:

5.1.1 On receipt of the GRN and physical verification from the Store, concerned QC personnel shall enter the details of sample in Packaging material sample inward register as per Annexure - I.

5.1.2 While entering the details of Physical Verification Report of all packaging material into sample inward register, check that name of Manufacturer is part of Approved vendor list. If the material is not received from the approved vendor then material shall not be sampled & intimation for the same shall be given to the Manager QC or his/her designee.

5.1.3 In case of the new consignment or any change in artwork or any change in size of material, the samples should be given for machine trials to packing department.

5.1.4 Assign the work of sampling to the Authorised Persons only, list of authorised persons shall be prepared as per Annexure - II.

5.1.5 Check the details given on physical Verification Report with the Manufacturer label on the packaging material boxes /rolls and the label affixed by the Stores on all 100 % containers.

5.1.6 Fill the sampling checklist as per Annexure - III.

5.1.7 Affix Yellow coloured "UNDER TEST" signed label, at least one label for each pellet of P.M. consignment.

5.1.8 Use sampling devices like scissors, Cutter, Knives for sampling.

5.1.9 Open the boxes / rolls as per $\sqrt{n} + 1$ where n in total no of boxes / rolls received or 5, whichever is more. Take the separated samples from loosebox or boxes / rolls are received in damaged condition.

5.1.10 If any boxes/ rolls found in damaged condition intimate the Packaging material Store In charge and QC In-charge for part Qty. Rejection & part Qty. Approval.

5.1.11 Carry out the sampling of all PM as per following sampling plan for acceptance quality level from each selected boxes of all packaging material as per current version of SOP.

Received Qty. (No.)	Sample Size (No.)
1 to 150	20
151 to 280	32
281 to 500	50
501 to 1200	90
1201 to 3200	125
3201 to 3200	200
10001 to 35000	315
35001 to 150000	500
150001 to 500000	800
500001 to Above	1250

5.1.12 Carry out the sampling as per the list prepared in Annexure-IV for destructive tests. Carry the sample to PM lab for testing as per specification. Destroy the remaining samples after completion of analysis & document the same.

5.1.13 Carry out the sampling of Primary packaging material under LAF bench provided in A/C area.

5.1.14 Close all the Boxes/ Rolls/ Bundles properly with BOPP tape after sampling, mark the

5.1.15 After completion of sampling, send the samples in Quality control department for further course of action.

5.2 Verification during Sampling

5.2.1 During sampling of the packaging material, check that all packaging material is received with proper packing, labelling and free from any unwanted contamination (i.e. free from oil spot, spitting spot, not in wet condition etc.).

5.2.2 Check on each box/Roll received with proper labelling and label should contain name of packaging material, supplier name, quantity and delivery date as per the challan.

5.2.3 Check that the boxes / Bags of all cartons / Catch covers / inserts/ Labels / Sticker labels should be preferably in a specific bundle pack with paper sleeve & packed in transport worthy corrugated shipper with sufficient cushioning material (if required) to avoid damage in transits.

5.2.4 Check that the plastic containers, plastic caps, Al. Caps, Droppers, should be packed in a polybag within a transport worthy corrugated shipper.

5.2.5 Check, all foils (Pain and Printed), PVC, PVDC rolls received in following manner:

5.2.5.1 Rolls shall be packed in poly bag or wrapped with a plastic film.

5.2.5.2 Rolls shall be packed in a transport worthy corrugate shipper with proper packing to avoid damage during transits.

5.2.5.3 Rolls should be free from telescopic, loose winding and edges of rolls are free from any damage.

5.2.5.4 For PVC & PVDC, plastic plugs are used in core side of rolls for protection of core.

5.2.6 Shrink film rolls should be packed in a poly bag or wrapped with transparent plastic film & pouch film rolls should be wrapped with plastic film or strong Kraft paper.

5.2.7 Winding direction should be as per approved drawing.

5.2.8 Check that corrugated box received is in proper condition, protected from rain, sun & dirt.

6.0 SAFETY & PRECAUTIONS:

Not applicable.

7.0 REVISION HISTORY:

RevisionNo.	Reason for Revision	Superseded from & Date
00	New	--------

8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

9.0 REFERENCES:

SOP "Acceptance quality level of packaging material"

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QC : Quality Control

% : Percentage

No. : Number

PVC : Poly Vinyl Chloride

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling and Verification of PM	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

PVDC : Polyvinyldine Chloride

PMQC : Packaging Material Quality Control

PM : Packaging Material

Qty. : Quantity

A.R No. : Analytical Report Number

BOPP : Biaxially oriented polypropylene

A/C : Air Conditioned

ID : Identification

LAF : Laminar Air Flow

ANNEXURES:

Annexure - I: Packaging Material Sample Inward Register

Annexure - II: Name of Authorized Persons For Sampling

Annexure - III: Sampling Check List For PM

Annexure - IV: Sample Qty. For Testing of Packaging Material In PM Lab

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling and Verification of PM	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE - I

PACKAGING MATERIAL SAMPLE INWARD REGISTER

A.R.No.	Date of Receipt	Name of the Materials	Name of Mfg./Supplier	Recepipt		Challan No. & Date	Date of Report	Approved / Rejected	Remarks	Sample Destruction		Name of Analyst
				Boxes/ Rolls	Qtty. (No.)					Date	Sign	

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling and Verification of PM	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE - II

NAME OF AUTHORIZED PERSONS FOR SAMPLING

S.No.	Name of Authorized Persons for Sampling

Authorized by:

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling and Verification of PM	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE - III
SAMPLING CHECK LIST FOR PM

A.R.No.: _____ Date : _____

S.No.	Description	Observation
1	Name of material	
2	Manufacturer	
3	Supplier	
4	Present in Approved Vendor list	
5	Packing Style as per plan	
6	No. of Container received	
7	Quantity received	
8	Condition of container	
9	Segregated container No. if any	
10	Total quantity Segregated if any	
11	No. of container sampled	
12	Quantity sampled for AQL	
13	Quantity sampled for Testing in Lab*	
14	Remark, if any	

* Sample to be taken from AQL sample

Sampled by :

Date :

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Sampling and Verification of PM	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE - IV
SAMPLE QTY. FOR TESTING OF PACKAGING MATERIAL IN PM LABORATORY

A.R.No.: _____ Date : _____

S.No.	Name of Packaging Material	Sample Quantity
1	Aluminum Foils (Printed / Plain)	0.100 Kg
2	Carton	25 No.s
3	Catch Cover	25 No.s
4	Labels / Sticker Label	25 No.s
5	Pack Insert	25 No.s
6	PVC/PVDC	0.500 Kg
7	Plastic container / Cap	10 No.s
8	Spike Cap	25 No.s
9	Corrugated Box	2 No.s
10	Thermocol Box	2 No.s
11	BOPP Tape	2 Meters