PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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

1.0 OBJECTIVE:

To lay down procedure for Sampling of Raw Materials for analysis.

2.0 SCOPE:

This SOP is applicable to all Raw Materials received.

3.0 RESPONSIBILITY - Execution - Executive QC

Checking - Assistant Manager

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 Receive the GRN (Goods Received Note) from Raw material Stores and make necessary entries in the raw material inward register.

5.2 Prepare the Raw material folder for the material received and fill the product details.

5.3 File the supplement pages such as copy of purchase order, excise documents, supplier's certificate of analysis, receipt cum inspection report etc. and GRN.

5.4 The concerned person shall take the RM folder and proceed for sampling.

5.5 Enter into the sampling area as per SOP.

5.6 Check the cleanliness of the sampling room.

5.7 Take the cleaned sampling devices, self-sealing bags or bottles, gloves and nose mask, labels etc. from the cabinet in the sampling room.

5.8 Ensure that the sampling device's cleaning status is OK and "cleaned" label is attached.

5.9 Switch ON the Laminar Air flow not less than 20 minutes before the actual sampling.

5.10 Ensure the reading of the negative pressure is between 0-5mm of water, intermediate is between 3-6 mm of water and HEPA filter pressure is between 7-15mm of water.

5.11 Take the containers inside and inspect the same for cleanliness and physical conditions.

5.12 Ensure that any Approved labels from the suppliers/manufactures are defaced by way of cross marking it.

5.13 Take one batch one product at a time into sampling room.

5.14 In case of any discrepancies inform the Manager QC and do the sampling only after the clearance from Manager QC.

5.15 Check the labels (including Quarantine label) and other details with the details in the GRN. In case of any discrepancies, inform Manager QC for further action.

5.16 Arrange the containers for sampling.

5.17 In case of active ingredients carry out the sampling as follows and simultaneously fill the raw material sampling report as Annexure - I

5.17.1 Sample all the containers.

5.17.2 Use appropriate sampling and safety devices.

5.17.3 Arrange one container at a time under LAF bench.

5.17.4 Check the material for the compliance as per the specification for description, colour, other physical characteristics and black particles.

5.17.5 Insert the sampler and withdraw the sample.

5.17.6 Collect about 100-500 mg samples in a small poly bag for unit identification purpose and labeled the bag with product and container number details.

5.17.7 Collect the balance quantity into big polythene bag for composite sample purpose.

5.17.8 Repeat the operation for further containers of the batch and collect the composite sample in composite sample bag and put the labeled as Annexure - II.

5.17.9 Mix the composite sample and take the required quantity of samples (Analysis sample, control sample and out lab samples) in a twin poly bag (Self sealing) with sample label duly filled.

5.17.10 Close the bags and containers and put “SAMPLED” stamp diagonally on the store label and paste under test label along with store label.

5.17.11 Put signature and date on the labels of the containers sampled.

5.17.12 Remove the containers from sampling area and record the activities in the sequential log as Annexure - III.

5.18 In case of excipients carry out the following procedures:

5.18.1 The sampling of the excipients shall be carried out either on site or in the sampling room and simultaneously fill the raw material sampling report as annexure -I.

5.18.2 Select a number of containers for sampling which shall be not less than $\sqrt{n}+1$, where ‘n’ is the total number of containers received.

5.18.3 Open the selected containers and check for description, colour, other physical characteristics and black particles or any abnormal properties.

5.18.4 Using an appropriate sampler, collect the samples from each container selected and make a composite sample, mix.

5.18.5 Take appropriate quantity from the composite sample in a twin self sealing sample bags duly labeled with sample details as Annexure - II.

5.18.6 Close the containers and put ‘SAMPLED’ stamp on the store label and paste under test label along with store label.

5.18.7 Mix the composite sample and take the required quantity of samples (Analysis sample, control sample and out lab samples) in a twin poly bag (Self sealing) with sample label duly filled.

5.18.8 Record the activity in sequential logbook as Annexure - III.

5.19 In case the sampling is required for Microbiology analysis, then sanitize the sampling device with 70% IPA and air-dry. During sampling, separately collect sample for microbiological analysis from the composite sample and identity accordingly.

5.20 For sampling the solvents use liquid sampler and collect sufficient samples from different levels of the container.

5.21 Solvent shall be sampled at the place of storage.

5.22 Shake the drums by tumbling before sampling and collect samples in clean dry bottles, for analysis only.

5.23 Check the samples for any foreign particles, colour or any phase formation (contamination).

5.24 Close the containers and put ‘SAMPLED’ stamp on the store label and paste under test label along with store label.

5.25 The retain sample for solvents need not be sampled.

5.26 Clean the sampler/devices as per SOP for cleaning of sampling devices and store the samplers in the designated place.

5.27 Sampling of Retest Materials:

5.27.1 The Stores shall send the intimation list for the materials due for retest at the beginning of every month.

5.27.2 On receipt of intimation from stores, arrange for sampling of materials that are due for retest.

5.27.3 The sampling shall be done either on any day in the month of actual due date or after.

5.27.4 The material may be used till the due date and RETEST label shall be put on the actual due date.

5.27.5 In case where sampling is done before the actual due date, strike out the old SAMPLED stamp (if any) on the containers sampled and put new SAMPLED stamp and sign it.

5.27.6 Where sampling is done on or after due date, ensure the previous approval labels are defaced and RETEST label is attached on store label.

5.27.7 Follow the sampling procedure as prescribed above (Points 5.5 to 5.25)

5.27.8 Select a number containers to be sampled

5.27.9 Sampling shall be done from 'x' number of containers using the formula $x = \sqrt{n} + 1$, where n is the number of containers available in a lot at the time of retesting.

5.27.10 Note: For Excipients, the containers selected at the time of original (Initial) analysis shall not be selected while sampling for retest material.

5.27.11 Sample only the samples required for analysis.

5.27.12 The material shall be sampled in sufficient quantity required for those tests, which mentioned in specification for the retesting.

5.27.13 In case of active material the sample shall not be sampled for unit identification (Spot identification) again.

5.27.14 Chemist shall keep the sample in Quality control in designated places and carry out analysis as per the Retest specification.

5.27.15 When the material is approved, the approval of the same in the system shall be given on or after the actual due date.

5.27.16 Deface the retest label and put the new Approval label over it on the container.

5.27.17 In case of any discrepancies, inform the Manager Quality Control for further follow up.

5.28 Carry the sample to QC dept. for further course of action.

5.29 Hand over the control samples to concerned QA personnel for handling of control samples.

6.0 SAFETY & PRECAUTIONS:

Not applicable.

7.0 REVISION HISTORY:

Revision No.	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:

Entry and Exit in Quality Control SOP

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QC : Quality Control

% : Percentage

IPA : Iso Propyle Alcohol

A.R. : Analytical Report

GIM : Goods Inward Memo

SS : Stainless Steel

HDPE : High Density Polyethylene

LAF : Laminar Air Flow

HEPA : High Efficiency Particulate Air

M.S : Material Safety

R M : Raw Material

Annexure - I: Raw Material Sampling Report

Annexure - II: Sample Label

Annexure - III: Sequential Log for Raw Material Sampling

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ANNEXURE - I

RAW MATERIAL SAMPLING REPORT

Item Code		Date of receive	
Item Name		A.R. No.	
Mfg. Batch No.		Quantity	
Mfg. Name		No. of container Receive	
Supplier Name		No. of container Sampled	
Mfg. Date		Sample Quantity	
Exp. Date		Control sample Quantity	

Packing details: {Fiberboard Drums / HDPE bags / Plastic bags / Laminated paper bags / M.S. container /S.S. container / Shipper / Glass bottle}

Details of Container Sampled

Identification test details:

1	11	21	31	41	51	61	71	81	91
2	12	22	32	42	52	62	72	82	92
3	13	23	33	43	53	63	73	83	93
4	14	24	34	44	54	64	74	84	94
5	15	25	35	45	55	65	75	85	95
6	16	26	36	46	56	66	76	86	96
7	17	27	37	47	57	67	77	87	97
8	18	28	38	48	58	68	78	88	98
9	19	29	39	49	59	69	79	89	99
10	20	30	40	50	60	70	80	90	100

Remark: _____

Sampled By / Date: _____ Checked By / Date: _____

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ANNEXURE - II

SAMPLE LABEL

Quality Control Department
SAMPLE
Item……
Batch No……
Qty./Batch size..…… ……
Mfg……
Signature……...Date…..……..

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ANNEXURE - III
SEQUENTIAL LOG FOR RAW MATERIAL SAMPLING

Date	Shift	Product	Batch No.	Cleaning		Checked By	Operation		Checked By	Batch Size	Remarks
				From	To		From	To			