STANDARD OPERATING PROCEDURE	
Department:	**SOP No.:**
Title: Sampling, Testing, Release and Rejection of Raw Materials	**Effective Date:**
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1.0 OBJECTIVE:

To lay down a procedure for sampling, testing, release & rejection of Raw materials.

2.0 SCOPE:

This procedure is applicable to sampling, testing, release & reject of Raw materials received.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control Department

Head -- Quality Control Department

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Sampling of Raw Materials:

5.1.1 Raw material sampling shall be initiated after receiving the "GRN" from stores.

5.1.2 QC personnel shall enter the material details in "starting material inward record'' as per Annexure-I and shall assign A.R. No. for each batch/lot of raw materials.

5.1.3 QC personnel shall prepare "QC UNDER TEST "labels as per received GRN for each container (Refer Annexure-II).

5.1.4 QC personnel shall go to the stores along with sampling kit, sampler's remark sheets and GRN.

5.1.5 QC personnel shall check the materials as per GRN.

5.1.6 Enter the sampling booth as per SOP.

5.1.7 Sampling of non- sterile material shall be carried out under R-LAF located in sampling area of stores.

5.1.8 QC personnel shall use a cleaned and dried sampling aid as follows.

Types of Raw material	Sample Device	Sample collection container
Non-sterile solid	SS Spatula/Sampling Thief	Polyethylene bag
Liquid / Solvent	Glass sampling rod or SS sampling rod or pipettes	Glass bottles

5.1.9 QC personnel shall open the containers or bags under the sampling booth individually and take out the sample as per sampling plan given at point 5.2.

5.2 Sampling Plan:

5.2.1 Refer the GRN received from raw material store, confirm the number of container, verify the details on the containers with GRN & check for damage ,seal integrity etc.

5.2.2 Sample shall be collected from top, middle & bottom of the layers from the drums for solid materials and for liquid/solvent, top and middle portion of the barrel / containers.

5.2.3 Material to be sampled in following manner viz.:

a) For identification test: Individual sample from each container.
(100 % sampling).

b) For Composite Sample (Assay & LOD/Water):
The consignment of raw material shall be divided in groups to ensure representative sampling for tests of assay and water/LOD.
A maximum of 5 containers shall be arranged in each group according to container number.
Withdraw the sample from top, middle & bottom of each container.
Collect the samples from individual container of each group in a single polybag with proper marking.
Close the mouth of the polybag and mix thoroughly by manual shaking.
For Example :
If a consignment consists of 100 containers of same batch, arrange the container no.1 to 5 in one group and container no.6 to 10 in another group and so on such that all containers are arranged in 20 groups. Sampling shall be done from each container of one group in a poly bag and mixed by shaking. Hence, a total of 20 samples from 20 groups shall be prepared for assay and water / LOD.

c) Final composite sample:
Withdraw appropriate quantity of samples equivalent to the required quantity from individual containers ensuring that approximately equal quantity are drawn from

individual containers and place the samples in polybag, appropriately labeled as per Annexure III.

- ❖ Close the mouth of the polybag and mix thoroughly by manual shaking.
- ❖ The personnel shall prepare the testing sample and the control sample
- ❖ The quantity shall be as per respective specification of the material.
- ❖ The samples that are hygroscopic in nature shall be first put in poly bag and further put in another seal bag and packed in LDPE container duly labeled with batch details.
- ❖ The samples that are light sensitive shall be first put in poly bag and further put in black poly bag and labeled.

5.2.4 The control sample shall be labeled and handled as per the control sample SOP.

5.2.5 ‘‘QC UNDER TEST’’ label shall be affixed on all the containers over “QUARANTINED” label in such a manner that the word “QUARANTINED” is covered and rest of the text matter is visible.

5.2.6 After affixing “QC UNDER TEST” labels on the containers / drums/ bags, these shall be transferred to “UNDER TEST” storage area meant for this purpose. The containers / drums / bags shall be transferred through trolley. (Small containers shall be transferred manually.)

5.3 Precautions:

5.3.1 Personnel shall take the following precautions:

5.3.1.1 Before sampling:

a) Sampling area is thoroughly cleaned after sampling of each product. (Only two persons in sampling booth at a time).

b) R-LAF of sampling booth shall be switched on at least 15 minutes before starting the sampling.

c) Ensure that the desired air pressure differentials are achieved as observed on the magnehelic gauges.

d) Ensure that the desired temperature & relative humidity is achieved.

e) Balance used to weigh the sample shall be calibrated on the day of sampling.

f) Personnel shall wear protective garments i.e. apron, cap, hand gloves and mask etc.

g) Hand gloves shall be discarded after each product sampling.

h) Only one batch shall be sampled at one time.

5.3.2.2 After Sampling:

a) Ensure that the sampled containers shall be closed and sealed properly.

b) The material supplied in drum with inner polythene bags shall be tied with pilfer seal and the drum shall be tightly closed with the help of lid and lock ring.

c) PVC woven bag and aluminum jar shall be placed in a clean appropriate size polybag. The polybag shall be tied with pilfer seal.

d) Switch off the R-LAF booth.

e) Clean R-LAF booth & sampling room.

f) Record the activity in sampling logbooks.

g) Cover the sampling devices in polybags & carry to stores washing area for cleaning.

h) Remove secondary gown, gloves, booties, head gear etc. in the personal airlock & exit.

5.4 Documentation for Sampling:

5.4.1 Sampler shall record his observation during sampling in “sampler’s remark sheet “ as given in Annexure -IV.

5.5 Testing of Raw Materials:

5.5.1 QC personnel shall perform the identification test for samples drawn from each container as per specification and standard test procedure.

5.5.2 For composite sample: Prepared by compositing samples from 5 containers. QC personnel shall perform Water / LOD and Assay test (wherever applicable) as per respective standard test procedure & specifications.

5.5.3 For final composite sample: QC personnel shall perform complete analysis as per respective standard test procedure & specification.

5.5.4 Raw data shall be recorded in the respective testing protocol.

5.5.5 After completion of analysis, all data shall be reviewed and certificates of analysis for each batch shall be prepared.

5.5.6 Only description and identification test shall be carried out incase if raw materials is transferred within the same location (From one block to other block), by ensuring the physical intactness of materials.

5.6 Release / Reject of Raw Material:

5.6.1 If material is approved, prepare " QC APPROVED " labels for each container as per Annexure-V and affix on each container / drum / bag over the " QC UNDER TEST" label in such a manner that the entire " QC UNDER TEST " label is completely covered by the " QC APPROVED " label.

5.6.2 If materials is rejected, prepare "QC REJECTED" labels as per Annexure-VI and affix on each container / drum / bag over the "QC UNDER TEST" label in such a manner that the entire "QC UNDER TEST " label is completely covered by the " QC REJECTED " label. Initiate the "Rejection Note" for respective consignment as per Annexure-VII.

5.6.3 Prepared one extra label each of "QC UNDER TEST", "QC APPROVED" or "QC REJECTED" for each A.R. No. & affix the same on the "Samplers Remarks Sheet" for reference. These shall be signed by concerned Personnel.

5.6.4 Send the rejection note to warehouse and ensure that the material is transferred to Rejected area.

5.6.5 Labels of "QC UNDER TEST", "QC APPROVED" & "QC REJECTED" shall be generated on computer.

5.6.6 In case of non-availability of computer due break down or any other reasons, hand written labels shall be prepared & affixed.

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6.0 ABBREVIATION(S):

QCD - Quality Control Department

SOP - Standard Operating Procedure

A. R. No.: Analytical Report Number

GRN : Goods Receive Note

LOD : Loss on drying

R-LAF : Reverse Laminar air flow

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure-I : Starting materials inward record

Annexure-II : QC UNDER TEST label

Annexure-III : Raw materials sample slip

Annexure-IV : Sampler's Remark sheet

Annexure-V : QC APPROVED labels

Annexure-VI : QC REJECTED labels

Annexure-VII : Rejection notes

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9.0 REVISION CARD:

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

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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ANNEXURE I

RAW MATERIAL INWARD REGISTER

S.No.	Date of Intimation	Name of materials	B.No.	Mfg. Date	Exp. Date	Qty. Received	Manufacturer	Sampled By	Challan No/Date	GRN No./date	A.R. No.	Date of Report	Analyst	Remarks

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ANNEXURE II

Under Test Label

QC UNDER TEST	
Item :	
B. No. :	Code :
Mfg. Dt. :	Exp. Dt. :
Qty. :	Unit :
Mfg. :	
Supp. :	
GRN No. :	GRN Dt.:
AR No. :	Cont. # :
Sampled By :	Date :

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ANNEXURE III

Raw Material Sample Slip for Analysis

SAMPLE FOR ANALYSIS					
Name	**:**				
B.No.	**:**			**AR No. :**	
Qty. Received	**:**				
GRN No. / Date	**:**				
Mfg. Date	**:**			**Exp. Date :**	
Mfg. By	**:**				
Supplier Name	**:**				
Container No.	**:**	of / Composite			
Sign / Date	**:**				

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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ANNEXURE IV

RAW MATERIAL SAMPLER'S REMARK SHEETS

Name of Material		**A.R. No.**	
Total no. of containers received		**GRN No. / Date**	
Qty. Sampled			

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1.	Storage condition	Temp & RH complies/does not complies		
2.	Packing (Please tick mark as appropriate)	a.	Drums / bottles / Carboy / barrels	
		b.	Fiber plastic drums with polybag inside	
		c.	PP woven bags with polybag inside	
3.	Packing condition (satisfactory / not satisfactory) (State observations if not satisfactory)			
4.	Container label details verification (State whether yes or no)	a	Pharmacopoeia Status (IP /BP/ USP/ IH / none)	
		b	Manufacturer's name	
		c	Batch number	
		d	Date of manufacturing	
		e	Date of expiry	
		f	Quantity	
		g	Container number (if any)	
		h	Storage conditions	
		i	Any other remarks	
5.	Physical Appearance of the material inside.	a	Presence of lumps	
		b	Any abnormal odour	
		c	Heterogeneity within same container / container to container (for solid material)	
		d	Foreign matter	
		e	Any other abnormality	
6.	Suppliers test certificates	Received / Not received		
7.	Approved vendor (Yes / No)			

Signature of Sampler / Date :

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ANNEXURE V

Approved Label

QC APPROVED	
Item :	
B. No. :	Code :
Mfg. Dt. :	Exp. Dt. :
AR No. :	
Qty. :	Unit :
Release Dt. :	
Retest :	
	QC Analyst :

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ANNEXURE VI

Rejected Label

QC REJECTED	
Item :	
B. No. :	Code :
Mfg. Dt. :	Exp. Dt. :
AR No. :	
Qty. :	Unit :
Reason :	
	QC Analyst :

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ANNEXURE VII

Date: _____

REJECTION NOTE					
Material Name	**:**		**AR No.**	**:**	
Batch No.	**:**		**Batch Size**	**:**	
Mfg. By	**:**		**Supplied By**	**:**	
Date Receipt	**:**		**Challan No./Date**	**:**	
GRN No.	**:**		**Date of Sampling**	**:**	
Reason for Rejection :					
Rejected Quantity:					
Analyzed By			**Manager Quality Control**		

cc: QA/ Warehouse/ Purchase/ Account