PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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

1.0 OBJECTIVE:

To lay down the procedure for Retesting of Raw Material.

2.0 SCOPE:

This SOP shall be applicable for Retesting of Raw Material.

3.0 **RESPONSIBILITY:**

3.1 Preparation - Executive QC.

3.2 Checking - Assistant Manager QC.

3.3 Approval - Manager QC

4.0 PROCEDURE:

4.1 Sampling of raw materials due for Retesting:

4.1.1 Retesting of raw material shall be initiated after receiving the intimation from warehouse

4.1.2 Warehouse Executive shall intimate to quality control department 15 days in advance on (Annexure I), so that material can be tested before the retest date. It is preferred to carry out the test before 7 days

4.1.3 Retest period / date should not exceed the actual expiry date/Use before declare by manufacturer.

4.1.4 Executive QC shall enter the material details in raw material retest inward record and shall assign new A.R. No. by putting a prefix R1,R2, R3 for each batch /lot to the original A.R.No.of raw materials for retesting 1st time, retesting 2nd time and retesting 3rd time respectively

4.1.5 The concerned person shall prepare Under test labels as per received intimation slips for each containers.

4.1.6 Executive QC shall enter in the warehouse area along with sampling kit.

4.1.7 Executive QC shall perform the sampling as per raw materials sampling SOP in respective area.

4.2 Sampling Plan:

4.2.1 Executive QC shall draw the sample from all individual containers and make a composite under the RLAF for complete analysis, and paste the label as per SOP “Sampling procedure

for RM".

4.2.2 Executive QC shall affix the "Under test" label on each sampled container for analysis.

4.2.3 Executive QC shall perform the test of Raw materials as per respective standard test procedures and specifications for the applicable following test only :

i) Assay

ii) Identification

iii) Water / LOD

iv) Chromatographic purity

v) Microbial test

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

4.2.5 If material is approved prepare Approved labels for each containers .

4.2.6 If material is rejected, prepare Rejected labels and affix on each packs on the particular batch above the "Under test label". Initiate the "Rejection Note" for respective materials.

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

4.3 Frequency for Retesting of Raw Materials:

4.3.1 All Active Raw materials shall be retested after six month from the date of release. The retesting schedule for the released material shall be maintained by Warehouse as per Annexure -III

4.3.2 Inactive raw material having microbial limit test shall be retested after six month from the date of release & Other Inactive raw materials shall be retested after one year from the date of release. The retesting schedule for the inactive material shall be maintained by Warehouse as per Annexure -IV.

5.0 SAFETY AND PRECAUTION:

Not Applicable.

6.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & Date

7.0 REFERENCES:

Not Applicable.

8.0 ABBREVIATIONS:

SOP : Standard Operating Procedure

QA : Quality Assurance

No. : Number

QC : Quality Control

Qty. : Quantity

RLAF : Reverse laminar air flow

A.R.No. : Analytical reference number

9.0 ANNEXURE:

Annexure-I: Intimation for Retesting

Annexure-II: Raw Material Retest Inward Record

Annexure-III: Retesting Schedule for active Raw material

Annexure-IV: Retesting Schedule for Inactive Raw material

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Annexure-I
INTIMATION FOR RETESTING

Date:

S.No.	Name of Material	AR No.	Retest date

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Annexure-II

RAW MATERIAL RETEST INWARD RECORD

RAW MATERIAL RETEST INWARD RECORD													
Sr. No	Date of Intimation	Name of Raw materials	B. No. / Lot No.	Mfg. Date	Exp. Date	Qty	Suppliers / Manufacturers	Retest date	Sampled By	AR No.	Date of Report	Analyst	Remarks

Annexure-III

RETESTING SCHEDULE FOR ACTIVE RAW MATERIAL

S.No.	Name of Material	AR No.	Released date	Retest date

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Annexure-IV

RETESTING SCHEDULE FOR INACTIVE RAW MATERIAL

S.No.	Name of Material	AR No.	Released date	Retest date