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

1.0 OBJECTIVE:

To lay down a procedure for Retesting of raw materials.

2.0 SCOPE:

This SOP is applicable to Retesting of raw materials in quality control department.

3.0 RESPONSIBILITY:

Officer, Executive, Section Head – Quality Control

Head – Quality Control

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 Retest date shall be intimated to quality control department well in advance, so that material can be tested before the retest date.

4.1.3 Retest period / date should not exceed the actual expiry date declared by the manufacturer. Extension of expiry date shall be reassigned for active raw material based on manufacturer supporting stability data or extended expiry date revised certificate of analysis.

4.1.4 When the vendor assigned retest/revaluation date, best before date, the material can be used for manufacturing, if it complies with the specification after retesting, and allocation of the next retest date should be same as on the certificate of analysis/evaluation data provided by the manufacturer with extended retest date or allocation of the next retest date should be 30 days till it complies with the specification.

4.1.5 In case of code-to-code and grade to grade transfer of material, a new retest date shall be allotted only if the tests like Assay/ RS are performed. Otherwise the previously allotted retest date shall be considered.

4.1.6 QC officer shall enter the material details in raw material retest inward record as per Annexure-I 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, 2nd time and 3rd time respectively.

4.1.7 QC officer shall prepare Under test labels as per received intimation slips for each containers as per SOP.

4.1.8 QC officer shall enter in the warehouse area along with sampling kit.

4.1.9 QC Officer shall perform the sampling as per SOP in the respective area.

4.2 Sampling plan and testing:

4.2.1 QC Officer shall follow the sampling plan for sampling and testing of the material as per SOP.

4.3 Frequency for Retesting of Raw Materials:

4.3.1 All Active Raw materials:

4.3.2 Retest date shall be assign 182 days from the date of release.

4.3.3 Inactive raw material having microbial limit test:

Retest date shall be assign 182 days from the date of release.

4.3.4 Other Inactive raw materials (Excipients, solvents & colour):

Retest date shall be assign 364 days from the date of release.

5.0 ANNEXURE (S):

Annexure-I Raw material retest inward record.

6.0 REFERENCE (S):

SOP: Sampling, Testing, Release & Rejection of Raw Materials

SOP: Preparation, approval, distribution, control, revision and Destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S)/DEFINITION (S):

RLAF : Reverse laminar air flow

A. R. No. : Analytical reference number.

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---

PHARMA DEVILS

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ANNEXURE I

RAW MATERIAL RETEST INWARD RECORD

S.No.	Date of Intimation	Name of Raw materials	B. No. / Lot No.	Mfg. Date	Exp. Date	Qty. Received	Suppliers / Manufacturers	Retest date	Sampled By	AR No.	Date of Report	Analyst	Remarks