



**STANDARD OPERATING PROCEDURE**

**Department:** Quality Control

**SOP No.:**

**Title:** Handling of Raw Material Control Sample

**Effective Date:**

**Supersedes:** Nil

**Review Date:**

**Issue Date:**

**Page No.:**

**1.0 OBJECTIVE:**

To lay down a procedure for handling of Raw material Control Sample.

**2.0 SCOPE:**

This procedure is applicable to control of raw materials, which is used for manufacturing of drug product.

**3.0 RESPONSIBILITY:**

Officer, Executive – Quality Control Department

Head – Quality Control Department

**4.0 DEFINITION(S):**

NA

**5.0 PROCEDURE:**

5.1 Solvents, acids, volatile materials and items will not be kept as control samples.

5.2 All control samples of raw materials shall be kept immediately after sampling.

5.3 Control sample shall be kept for all the batches of raw materials used in manufacturing of drug products.

5.4 Quantity required for two complete analysis shall be kept as control sample.

5.5 Sample shall be kept in a clean self-sealing bags or plastic bottles or suitable packing as specified.

5.6 Label the container as per specimens label given in Annexure-I.

5.7 Details shall be entered in control sample inward record as per Annexure-II

5.8 Sample shall be arranged according to A. R. No. wise.

5.9 Control sample shall be retained for a period of 1 year after the expiry of raw material .If expiry date is not mention on the raw material, it shall be retained for five years from the date of release.

5.10 All the control samples shall be stored below 25°C or as specified.



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- 5.11 Temperature of the control sample room shall be monitored twice in a day.
- 5.12 After completion of the control period, the sample shall be destroyed as per SOP and detail shall be recorded as per Annexure-II.

**6.0 ABBREVIATION(S):**

QCD - Quality Control Department  
SOP - Standard Operating Procedure  
A. R. No: - Analytical Reference Number

**7.0 REFERENCE(S):**

NA

**8.0 ANNEXURE(S):**

Annexure-I: Control sample label.  
Annexure-II: Control sample inward and destruction record

**9.0 REVISION CARD:**

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

