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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

Head – Quality Control

4.0 PROCEDURE:

4.1 Gases, corrosive, flammables, acids, volatile materials and liquid items should not be kept as control samples.

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

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

4.4 Quantity required for two complete analyses shall be collected as control sample.

4.5 Control samples of the solid materials shall be collected in the double polythene bag labeled with batch details, which will be further packed in container labeled and sealed.

4.6 If the material is light sensitive, same shall be collect in the double polythene black colour bag labeled with batch details, which will be further packed in triple laminated pouch, labeled and sealed.

4.7 Label the container as per specimen label given in Annexure-I.

4.8 After preparing the control samples in sampling booth, the samples shall be taken to control sample room for storage.

4.9 The control samples of materials that are bulky may be kept separately and the shippers shall be labeled accordingly.

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

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4.11 For better control and monitoring, the details shall be entered A. R. Number wise as entered in the starting material inward register.

4.12 The entries for material those are not mentioned in step No. 4.1 and the transfer entries where no control sample is kept shall be recorded as 'NA' or 'Not applicable'.

4.13 Control sample shall be retained for a period of 5 year.

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

4.15 Temperature of the control sample room shall be monitored twice in a day.

4.16 After completion of the control period, the sample shall be destroyed as per SOP and detail shall be recorded as per Annexure-II.

4.17 Control sample shall be withdraw for R&D and Analyst Validation through the Requisition Slip and Maintain the record as per Annexure IV

5.0 ANNEXURE (S):

Annexure-I: Specimen label for control sample.

Annexure-II: Control sample inward and destruction record.

Annexure-III: Control sample withdraw requisition slip.

Annexure-IV: Control sample withdraw record.

6.0 REFERENCE (S):

SOP: Disposal of leftover sample after analysis

SOP: Preparation, Approval, Distribution control, revision and Destruction of Standard operating Procedure (SOP).

7.0 ABBREVIATION (S)/DEFINITION (S):

A. R. No: Analytical Reference Number

SOP: Standard Operating Procedure

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REVISION CARD

S.No.	Revision No.	Revision Date	Details of Revision	Reason (s) for Revision	Reference Change Control No.
01	00	---	---	New SOP	---

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ANNEXURE I
SPECIMEN LABEL FOR CONTROL SAMPLE

CONTROL SAMPLE	
Item :	
B.No/Lot No.:	A.R.No:
Mfg.Date:	Exp. Date:
Retained upto:	
Name of Mfg:	
Name of Supplier:	
Sample Qty:	Sampled By/Date:

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ANNEXURE II
CONTROL SAMPLE INWARD & DESTRUCTION RECORD

S.No.	Name of Raw materials	B.No. / Lot No.	Mfg. Date	Exp. Date	A. R. No.	Retained upto	Sign/ Date	Date of Destruction	Destroyed By	Checked By

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ANNEXURE III
CONTROL SAMPLE WITHDRAW REQUISITION SLIP

S.No.	Product Name /Material Name	Date	Batch No. /A.R.No.	Qty.	Remarks

Purpose: _____

Prepared By: **Authorized By:**

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ANNEXURE IV

CONTROL SAMPLE WITHDRAW RECORD

S.No.	Name of Raw materials	B. No. / Lot No.	Mfg. Date	Exp. Date	A. R. No.	Reason of Withdraw	Qty. Withdraw	Date of Withdraw	Withdraw By	Checked By