DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Retention and Disposal of Documents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To establish and implement a procedure for retention and disposal of documents used in various departments.

2.0 SCOPE:

This SOP is applicable to the master document and related data available in company.

3.0 RESPONSIBILITY:

Executive - Quality Assurance

Head - Quality Assurance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Retain the master documents and related data for the retention time mentioned as per Annexure-II.

5.2 Ensure that retention documents are readily available throughout the period of retention to trace the information. All raw materials, both actives and excepients shall be procured only from approved suppliers.

5.3 Ensure that the integrity of the documents are not affected by storage condition throughout the period of retention.

5.4 Raise document disposal proposal after the retention period.

5.5 Get approval from Manager -QA for disposal of these documents.

5.6 Enter the details of the documents to be disposed in ‘Document Disposal Record’ (enclosed Annexure-I).

5.7 Send the documents along with copy of approved document disposal record to housekeeping department for destruction either by Shredding.

5.8 Ensure that documents are destroyed.

5.9 Retain the original copy of the document disposal record for reference.

6.0 ABBREVIATION(S):

BMR – Batch Manufacturing Record

BPR – Batch Packing Record

QA – Quality Assurance

7.0 REFERENCE(S):

NA

8.0 ANNEXURE (S):

ANNEXURE I: Document disposal details

ANNEXURE II: Retention time of documents

9.0 REVISION CARD:

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

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Annexure I

DOCUMENT DISPOSAL RECORD

Name of the Department:

Type of document (Tick (!) the appropriate)

- □ Standard Operating Procedure
- □ Qualification and Validation (Protocol & Reports)
- □ Calibration Reports
- □ BMR / BPR
- □ Site Master File
- □ Change control proposals
- □ Control sample records
- □ Training records
- □ OOS / NCR/Deviation records
- □ Pest control records
- □ Maintenance related records
- □ Other Records
- □ Usage Log Books (Equipment and Instruments)
- □ Analytical Reports, COAs and supporting data.
- □ Other QC Records (Specifications, STP, Method of analysis, RM/PM/FG Inward records, Stability records)
- □ Validation Master Plan
- □ Complaint files / recall
- □ Destruction records
- □ Self-Inspections reports
- □ Vendor audit reports
- □ Annual Product Review
- □ MMF/ Master BMR, BPR
- □ Warehouse Records (GRN, Inward/Stock register)

Brief details of the documents to be destroyed

Approved By(Manager-QA):

Disposal	Name	Signature	Date
Done by			
Checked by (QA)			

Annexure II

RETENTION TIME OF DOCUMENTS

S.No.	Document Details	Retention Time
1	Standard Operating Procedure	Permanent
2	Qualification and Validation (Protocol & Reports)	Permanent
3	Calibration Reports	6 Years
4	BMR/BPR	Expiry + 1 Year
5	Usage Log Books (Equipment and Instruments)	6 Years
6	Analytical Reports, COAs and supporting data.	Expiry + 1 Year
7	Other QC Records (Specifications, Method of analysis, RM/PM/ FG Inward records, Stability records)	6 Years
8	Site Master File	Permanent
9	Validation Master Plan	Permanent
10	Complaint files / recall	6 Years
11	Change control proposals	Permanent
12	Destruction records	Permanent
13	Control sample records	6 Years
14	Self-Inspections reports	6 Years
15	Vendor audit reports	Permanent
16	Training records	6 Years
17	OOS / NCR/Deviation records	6 Years
18	Annual Product Review	Permanent
19	Pest control records	6 Years
20	MMF/ Master BMR, BPR	Permanent
21	Warehouse Records (GRN, Inward/Stock register)	6 Years
22	Maintenance related records	6 Years
23	Other Records	6 Years
24	Dossiers filed	Permanent