STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Document Storage Period	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE

To lay down the Procedure for Document Storage Period.

2.0 SCOPE

This Procedure applicable to Quality Assurance Department.

3.0 RESPONSIBILITY

Executive – Quality Assurance

4.0 ACCOUNTABILITY

Head - Quality Assurance

5.0 PROCEDURE

5.1. The Batch Manufacturing Records (BMRs) and Batch Packing Records (BPRs) along with all the related documents shall be stored in the archive of Quality Assurance department for a period of one year from the expiry date, as per the SOP (Title: Procedure for Batch record Docket Archival).

5.2. The following Master Records shall be archieved in Quality Assurance as Permanent record

- 5.2.1 Product Manuals for Drug product.
- 5.2.2 Site Master Files & Validation Master files (SMF's & VMF's).
- 5.2.3 External Agency Audit records/reports.
- 5.2.4 Manufacturing Licence Documents.
- 5.2.5 Drug Master Files (DMF's)/Dossiers.
- 5.2.6 Standard Operating Procedures (SOP's).
- 5.2.7 Method of Analysis (MOA's).
- 5.2.8 General Testing Procedures (GTP's).
- 5.2.9 Validation Protocols (Cleaning Validation, Analytical Method Validation, Process Validation, Utility Validation, Equipment Qualification Protocols, etc.).
- 5.2.10 Empty Batch Manufacturing Records & Batch Packing Records (BMR & BPR's).

5.3. All Warehouse Records viz, Stock cards, GMP Records, Dispatch Records, Central excise Documents, etc., shall be preserved for a period of five years in archives of Ware house.

5.4. All Quality Control records viz, Analytical Reports, Analytical Method Development Reports, Instrument Calibration Records, Reagent/Standard Preparation Records, RM, PM In process/Finished Product Registers, Stability Test Reports shall be preserved for a period of five years in archives of Quality Control department.

5.5. All Engineering Records viz, Gauge Calibration Records, Equipment/Utility Qualification records, Equipment / Machine Logs, Filter Cleaning Records, Break Down /Preventive Maintenance records, etc. shall be preserved for period of five years in archives of Engineering department.

5.6. The records of Personnel department viz, Administration record, Medical Checkup records shall be preserved permanently in archives of personnel department. Other records viz., Area Cleaning Records, Disinfectant/detergent usage records, Pest control Records, Cleaning of Linen/Chappals/Shoes records, Scrap Collection records, etc. are preserved for period of five years in archives of Personnel department.

5.7. All Production Records viz., Equipment Operation and Cleaning log, Area Monitoring records, Balance Calibration Records, Batch Manufacturing& Batch Packing Registers, Tools/spares records etc. shall be preserved for period of five years in archives of Production department.

5.8. All Formulation Research Development Records viz., Product Development records shall be stored permanently in the archive of Formulation Research Development. Other Formulation Research Development Records like Equipment Operation and Cleaning log, Area Monitoring records, Trail/ Laboratory Batch Records, etc., shall be preserved for period of five years in archives of Formulation Research Development Department.

5.9. The GMP Records viz., Self Inspection Records, Vendor Documents, Deviation Records, Non-Conformance Records, Out of Specifications, Market Complaints Records, Product Recall Records, Signature Log, Validation Reports (Process, Cleaning, Equipment /Utilities), IQA Schedule, etc., shall be preserved for a period of five years in archives in Quality Assurance Department.

5.10. GMP records viz., Training Records are archived till the employee is in service.

5.11. Change Control Records shall be preserved permanently in Quality Assurance Department.

5.12. Documents shall be stored in a separate room under lock and key.

5.13. Access to the stored documents shall be restricted and controlled by the concerned department head.

5.14. Incase of all official Master Records and Batch Records which are stored in the archives of Quality Assurance, the access shall be made only after due authorizations from Head-Quality Assurance.

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Document Storage Period	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

5.15. Destruction of documents after its expiry of storage period shall be done after obtaining permission from Head – QA and such records shall be maintained as per Annexure –I

6.0 ABBREVIATIONS

IQA – Internal Quality Audit
GMP- Good Manufacturing Practices
RM- Raw Material
PM-Packing Material
QA-Quality Assurance

7.0 ANNEXURES

Annexure-I Document Destruction Approval Form.

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Document Storage Period	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE I
DOCUMENT DESTRUCTION APPROVAL FORM

Date:

From Department		**To**	Quality Assurance

Kindly verify the following documents, which are due for destruction.

S.No.	Title	Storage Period		Remarks
		From	To	

Sign/Date: _____
(Department Executive)

Authorized by/On: _____
(Department Head)

Quality Assurance Verification & Approval			
Documents Verified by		On	
Documents certified for destruction by Head – QA		On	
Destruction Done by		On	
Destruction Witnessed by		On	
Destruction Mode			