PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

1.0 OBJECTIVE:

To lay down a Procedure for Document Retention Period.

2.0 SCOPE:

This Procedure applies for Retention of Critical Documents in …….

3.0 RESPONSIBILITY:

Officer /Executive-Concern department: To follow SOP Accordingly.

HOD-Concern department: To ensure Implementation of SOP.

4.0 ACCOUNTABILITY:

Head-QA.

5.0 PROCEDURE:

5.1 MASTER COPY OF BMR/BPR AND STPs:

Obsolete version of master copy of BMR/BPR and STP shall be retained forever.

5.2 FILLED BMR AND BPR:

Filled copy of BMR and BPR shall be retained for expiry of product plus one year or minimum five years from the date of completion which is more.

5.3 MASTER COPY OF SOP:

Obsolete version of SOPs shall be retained forever.

5.4 MACHINE LOG BOOK:

Machine logbook shall be retained for expiry of product plus one year or minimum five years from the date of last entry which is more.

5.5 CHANGE CONTROL, DEVIATIONS, NON COMPLIENCE, MARKET COMPLAINT AND PRODUCT RECALL RECORD:

Record of Change control, Deviation, Non compliance, Market complaint and Product recall shall be retained forever.

5.6 **SITE MASTER FILE:**

Site master file shall retained forever.

5.7 **VALIDATION DOCUMENT:**

All validation related documents including BMR/BPR of validation batches should be retained forever.

5.8 **PRECAUTION FOR DOCUMENTS TO BE RETAINED FOREVER:**

In case the hard copy of any document is not possible to retain for long time due to un-avoidable reasons, the document shall be scanned on computer and record shall be kept forever on CD.

In case scanning of documents in not possible due to any reason then a duplicate copy shall be prepared, approved by Head-QA or his designate and shall be kept along with original copy.

5.9 **PRECAUTION FOR DOCUMENTS TO BE DESTROYED:**

Before destruction of any document, QA Head or his designate shall ensure that no issue pending related to regulatory and/or internal/external investigation(s) against the respective document.

In case any investigation is under proceeding or pending, in such case the document shall be destroyed after completion of investigation(s).

6.0 ABBREVIATIONS:

SOP - Standard Operating Procedure
QA - Quality Assurance
BMR - Batch Manufacturing Record
BPR - Batch Packing Record.
STP - Standard Test Procedure
CD - Compact Disc

7.0 CROSS REFERENCES:

NA

8.0 REFERENCES:

In-House

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9.0 ATTACHMENTS:

NA

10.0 CIRCULATION LIST

Quality Assurance

Production

Engineering

Quality Control

Warehouse

Personnel & Administration

Purchase

Account

11.0 REVISION HISTORY:

SOP NUMBER	REASON FOR CHANGE	VERSION NUMBER	SUPERSEDES	CHANGE CONTROL No.
	New SOP	01	NIL	NA