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

1.0 OBJECTIVE:

To lay down a procedure for Document control.

2.0 SCOPE:

This procedure is applicable to all type of documents control such as Batch Manufacturing Records (BMR's), Batch Packing Records (BPR's), Standard Testing Procedures (STP's), Specification, General Test Procedures (GTP's), Formats and Standard Operating Procedures (SOP's) by Quality Assurance.

3.0 RESPONSIBILITY:

Officer/ Executive – Quality Assurance

Head – Quality Assurance

4.0 DEFINITIONS:

NA

5.0 PROCEDURE:

5.1 Batch Manufacturing Record (BMR) and Batch Packing Record (BPR):

5.1.1 The master copies of all approved BMR/BPR's shall be available in QA Department.

5.1.2 The issue, control and retrieval of BMR/BPR shall be carried out as per the procedures given in the SOP.

5.2 Standard Testing Procedures (STP), Specification and General Test Procedures (GTP):

5.2.1 The master copies of all approved STP, Specification and GTP shall be available in QA Department.

5.2.2 The issue, control and retrieve of STP, Specification shall be carried out as per the procedures given in the SOP and GTP as per the procedures given in the SOP.

5.3 Formats:

5.3.1 The master copy of formats shall be stamped by approved seal and shall be available in QA Department.

5.3.2 The issue, control and retrieval of format shall be carried out as per the SOP.

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5.4 Revision of documents, retrieval and destruction:

5.4.1 The BMR, BPR, STP, Specifications, GTP, formats and SOP can undergo change or revision as per the various internal or external requirements.

5.4.2 After preparation of revised document, it shall be in draft form and circulated to respective department for checking.

5.4.3 Document shall be revised according to the comments and then corrected document shall be approved by QA head or his designee.

5.4.4 Whenever this document takes place, the QA personnel shall ensure that the new document is having the current version number.

5.4.5 QA shall ensure that the revised document is completed in all respects before its approval and also stamped as ‘Master copy’ in red colour ink.

5.4.6 Simultaneously, the previous master document is removed and marked as ‘Obsolete’ in red colour ink.

5.4.7 The new ‘Master copy’ shall be copied and marked/stamped as required and described above.

5.4.8 QA personnel shall ensure the retrieval of superseded documents and shall issue the new document.

5.4.9 On receipt of the old copies of the document from the various departments, QA shall retain only the obsolete master copy and destroy all the other copies.

5.4.10 The entire obsolete master copies shall be stored indefinitely in order to maintain the history of the change of the documents.

5.4.11 Filled and executed document will be retained in QA department.

6.0 ANNEXURE(S):

Nil

7.0 REFERENCE(S):

NA

8.0 ABBREVIATION(S):

QA: Quality Assurance

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QC: Quality Control

SOP: Standard Operating Procedure

9.0 REVISION CARD:

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