STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Preparation, Approval, Distribution, Control, Revision and Destruction of General Test Procedures	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for preparation, approval, distribution control, revision and destruction of General test procedures.

2.0 SCOPE:

This procedure is applicable to Quality Control department and serves as guidelines for its preparation, implementation and control of General test procedures used for analysis.

3.0 RESPONSIBILITY:

QC personnel - To prepare and check the general test procedures.

QA personnel & Head -QC – To review the general test procedures.

Head QA – To approve the general test procedures.

4.0 PROCEDURE:

4.1 Preparation of General Test Procedures:

4.1.1 Each general test procedure shall be prepared by the QC personnel in the format as per Annexure - I.

4.1.2 Standard A4 size (Width: 8.27” and Height: 11.69” approximately) white paper shall be used.

4.1.3 The text of general test procedures shall be in “Arial” font in a clear, unambiguous, easy to understand and easy to follow language.

4.1.4 The general test procedures shall consist of the following sections but not limited to:

- ***Scope,*** which shall give the applicability of the general test procedures
- ***Apparatus,*** which shall list all the apparatus involved in the preparation/ standardization procedures.
- ***Reagents,*** which shall list all the reagents, involved in the preparation/ standardization procedures.
- ***Preparation/standardization,*** which describes the preparation/ standardization with calculation, is applicable to the volumetric solutions only.
- ***Method,*** which shall include the detailed procedures of the general test procedures along with calculation if applicable.
- ***Reference,*** gives the reference of the general test procedure.

4.1.5 Each general test procedure shall include the revision card giving the details, revision no., change

control no., effective date, details of revision and reasons for revision, which shall be retained with the master copy for reference and shall not be part of the distributed copies.

4.1.6 A specimen of the "Revision Card" is given in Annexure–I.

4.1.7 The header for general test procedures shall include the following sections:

- Each document shall be printed with "***RESTRICTED CIRCULATION***" on the top right hand side corner, above the header.
- The header of each document shall contain the ***Name of Company*** and site address along with ***Logo*** on the top right hand side corner.
- The next section is the ***GTP No.*** in which is first 10 digits refer to general test procedure number and last 2 digits refer to revision no., represented as:

G	T	P	/			/				-		

SECTION Sequential No. Revision No.

- The first three digits "GTP" represent the general test procedures.
- The fourth digit is a slash "/".
- The fifth and sixth digit represents the section of the general test procedure:
  - VS for general test procedures for volumetric solutions
  - RF for general test procedures for raw materials and finished products
  - PM for general test procedures for packaging materials
- The seventh digit is a slash "/"
- The eighth to tenth digit represents the sequential number which shall start with "001" for the first GTP and proceed sequentially irrespective of the section of the general test procedure.
- The eleventh digit is a dash "-"
- The twelfth and thirteenth digit represents the revision no., which shall start with "00" for the first version followed by sequential numbers for each subsequent revision.

- ***Supersedes,*** shall be the document number which precedes this document. In case of new documents, it shall be printed as "Nil"

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- ***Effective Date,*** shall be the month & year when this GTP is scheduled to be effective.
- ***Review Date,*** shall be type as the month and year for review (Two years from the date of issue). However any changes in the document before the review date may be done due to changes in pharmacopoeia or regulatory bodies. In that case, it shall be done through a change control procedure and due change in the revision number.
- ***Page No,*** shall be the sequential page no. indicate as the current page no. of total no. of pages.

4.1.8 The middle section of first page shall include the general test procedures approval.

4.1.9 The footer of the document shall include the signatures of the persons responsible for preparing, checking and reviewing the documents as defined in the "Responsibility". The name, designation and department name of the respective persons shall be preprinted in the format.

4.1.10 A draft general test procedure shall be prepared and given to the designated personnel for checking.

4.1.11 After incorporating all the corrections, the final print shall be taken and distributed to the designated persons for their approval.

NOTE: Each signatory shall sign in blue pen in full / initial and put the date of signature.

4.2 Distribution and control procedure:

4.2.1 Only an approved document shall be considered for distribution and control.

4.2.2 The original document shall be retained by the QA department in safe custody under lock and key.

4.2.3 The original document shall be stamped as "MASTER COPY" in red ink on the top right hand side corner of all the pages.

4.2.4 Photocopy of the "MASTER COPY" shall be used for the distribution purpose. All photocopies shall be stamped as "CONTROLLED COPY/DEPT. CODE NO." in red ink at the center bottom portion on all the pages.

4.2.5 It shall be signed by QA person controlling the GTPs and allot a specific number to each department i.e. department code number.

NOTE: The specimens of the stamps used for the control and distribution of the documents and department code no. is attached to SOP.

4.2.6 The distribution of the documents shall be controlled by the issuing personnel of the QA department.

4.2.7 The details of distribution shall be entered in their respective distribution format. The details of the format are given in SOP.

4.2.8 Incase of issuance of general test procedures, which cannot be retrieved, only "UNCONTROLLED COPY" shall be given.

4.2.9 The "UNCONTROLLED COPY" shall be prepared by photocopying the "MASTER COPY" and stamping as "UNCONTROLLED COPY" in black ink on the bottom right hand side corner of all the pages.

4.3 Revision procedure:

4.3.1 Revision of general test procedures shall be done at any time within the two years of the issue but must necessarily be reviewed at the end of two years.

4.3.2 The revision shall be initiated through the change control procedure.

4.3.3 A draft General test procedure shall be prepared incorporating all the required changes and given to the designated personnel for checking.

4.3.4 After incorporating all the correction, the final print shall be taken and distributed to the designated persons for their approval.

4.3.5 After finalization of the document, it shall be distributed as per procedure described in steps 4.2.

4.3.6 The personnel responsible for the distribution of the revised documents ensure reconciliation of previous distributed copies and destroy the "CONTROLLED COPY/DEPT. CODE NO." GTP copies received from respective departments and enter the details in the respective format.

4.3.7 The "MASTER COPY" maintained in the QA department shall be stamped as "OBSOLETE" in red ink in the center of all pages and stored.

4.4 Destruction Procedure:

4.4.1 The retrieved copies of general test procedures shall be destroyed by any one of the following methods.

- Complete shredding
- Incineration

4.4.2 The issuing person in the QA department shall be responsible for entering the issuance in the respective format.

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5.0 ANNEXURE (S):

Annexure – I : Template for General Test Procedures

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution, control, revision and destruction of Standard Operating Procedure.

SOP: Document Control.

7.0 ABBREVIATION (S)/DEFINITION (S):

GTP : General Test Procedure

QA : Quality Assurance

QC : Quality Control

SOP : Standard Operating Procedure

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---

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ANNEXURE I

TEMPLATE FOR GENERAL TEST PROCEDURES

Header part:

GENERAL TEST PROCEDURE Reference SOP		
GTP No.		**<Title of GTP>**
Supersedes		
Effective Date		
Review Date		
Page No.		

Approval for first page only:

Approved By	
Head - QC	**Head - QA**

Footer part:

Prepared By	Checked By	Reviewed By
QC	QC	QA

For revision Card:

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.

Footer part:

Prepared By	Checked By	Reviewed By
QC	QC	QA