DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure.

2.0 SCOPE:

Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure at ……..

3.0 RESPONSIBILITY:

QA (Officer/ Executive): Preparation, Distribution (to Respective Departments), Revision, Retrieval & Destruction of this SOP.
Control and Issuance of STS, STP and GTP.

QA Manager : Review, Approval, Training and Effective implementation of this SOP in all the applicable areas.

QC (Officer/ Executive) : Preparation of STS, STP and GTP.

QC Manager : Review and Implementation of STS, STP and GTP.

4.0 ACCOUNTABILITY:

Head QA: For Approved of this SOP and Training and Effective Implementation of this SOP
Custodian of soft and hard copy of all Master STS, STP and GTP.

Head QC: Approval of STS, STP and GTP, ensure Training and Implementation of SOP.

5.0 DEFINITION:

Standard Test Specification (STS):

Standard Test Specification is defined as a list of Tests, References to Analytical Procedures and appropriate Acceptance Criteria which have Numerical Limits, Ranges or other criteria for the tests described.

Standard Test Procedure (STP):

Standard Test Procedure is a method for a test, such as a physical test, chemical test, Instrumental, Microbiological test or statistical test. It is a defined procedure that produces a test result.

General Test Procedure (GTP):

General Test Procedure is a general method of analysis applicable for some routine tests such as a Average Weight, Uniformity of weight, Loss on Drying, Water/ Moisture Content, MLT, Sterility, BET etc.

6.0 PROCEDURE:

6.1 PREPARATION OF STANDARD TEST SPECIFICATION (STS), STANDARD TEST PROCEDURE (STP) AND GENERAL TEST PROCEDURE (GTP):

6.1.1 STS, STP and GTP shall be written in English Language by using Microsoft Word.

6.1.2 STS, STP and GTP shall be initiated by a responsible person of Quality Control Department with reference of related document such as Pharmacopoeia and Guidelines published by various Regulatory Authorities.

6.1.3 Initiator shall prepare the draft of STS, STP and GTP and send to the Manager/ Designee for review.

6.1.4 Manager/Designee shall check the draft STS, STP and GTP for Accuracy, Adequacy, Correctness and Completeness.

6.1.5 Upon receipt of the comments (if any), the same shall be incorporated by initiator in the draft STS, STP and GTP.

6.1.6 Final soft copy of draft STS, STP and GTP shall be provided to QA.

6.1.7 QA shall take the printout of this STS, STP and GTP for signature.

6.1.8 Print out of STS, STP and GTP shall be provided to QC Departments for signature i.e. Prepared by, Checked by.

6.1.9 Upon signature of Prepared By, Checked by signed off STS, STP and GTP shall be sent to Head QA for Approval.

6.1.10 Soft Copy of all draft STP and GTP prepared by the QC Department shall be transferred to Head QA and shall be deleted in presence of QA person.

6.1.11 Material (API, excipients & packaging) & Finished Products name shall be mentioned in full form (i.e. abbreviation not allowed) in STS & STP as defined in respective pharmacopeia and

reference documents like drug master file in case in house material & innovator in case of in house finished product etc.

6.1.12 Acceptance criteria of all test parameters in STS & STP shall be referred from respective pharmacopeia & technology transfer documents (LL client) etc. as following:

6.1.12.1 Digit after decimal

6.1.12.2 Descriptive

6.1.12.3 Shelf life & Release Limits criteria

6.1.12.4 Storage Condition

6.1.12.5 Any other if specified.

6.2 DESIGN OF STS, STP AND GTP:

6.2.1 All STS shall contain Header, Footer and Body, Specimen format of Standard Test Specification for Raw Material, In–Process products , Packaging Material, Finished Product and Stability study, Water as shown in **Annexure-I, II, III, IV, V & XIV** respectively.

6.2.2 All STP shall contain Header, Footer and Body. Specimen format of Standard Test Procedure for Raw Material, In–Process Products, Packaging Material, Finished Product and stability study, Water as shown in **Annexure-VI, VII, VIII, IX, X & XV** respectively.

6.2.3 All GTP shall contain Header, Footer and Body, as per Specimen format of **"General Test Procedure"** as shown in **Annexure-XI** respectively.

6.2.4 All the pages shall contain Name, Signature, Date and in column provide in Footer part.

6.2.5 All STS, STP and GTP Master Copy shall be printed on A4 size Off-white colored Executive Bond Paper using **"Times New Roman"** Font with Black Ink.

6.2.6 Printing shall be done on one side of the paper only.

6.2.7 Paper Width 8.5", Height 11.5" or 11" (Paper Size Custom) and Margin Top 0.2", Left 0.6", Right 0.4", and Bottom Margin 0.2".

6.2.8 All STS, STP and GTP contents shall be covered by Single Borderline.

6.2.9 Line Spacing between two points or title and subtitle shall be 1.0 / 1.5 and font style shall be Times New Roman 12 font.

6.2.10 FONT SIZE OF HEADER, FOOTER AND BODY CONTENTS (STS, STP and GTP):

NAME OF CONTENT	FONT SIZE
HEADER:	
Name of the Organization and Location	16 Capital and Bold
Logo (On Left Hand Side Corner of the Page)	Height-0.75'' & Width-0.63"
Restricted Circulation	08 Running and Bold
Raw Material / In-Process / Semi Finished / Packaging Material / Finished Product/ Shelf life Specification and STP	12 Capital and Bold
General Test Procedure	12 Capital and Bold
BODY:	
Main Heading and Table Heading	12 Capital and Bold
Sub Heading	12 Running and Bold
Table Contents Except Headings	12 Running and Normal
FOOTER:	
Prepared By Officer / Executive QC, Checked By Manager QC, Approved By Head QA.	12 Running and Bold
Name, Sign and Date.	12 Running and Bold
Format No.	10 Capital and Normal

6.3 TYPE OF STANDARD TEST SPECIFICATION AND STANDARD TEST PROCEDURE:

6.3.1 Standard Test Specification:

6.3.1.1 STS shall be divided into five types as Raw Material, In–Process products, Packaging Material, Finished Product, Stability study and Water.

6.3.1.2 Raw Material Specification shall be prepared as per format **"Raw Material Specification"** as shown in **Annexure-I**.

6.3.1.3 In-Process Product Specification shall be prepared as per format **"In-Process Product Specification"** as shown in **Annexure-II**.

6.3.1.4 Packaging Material Specification shall be prepared as per format **"Packaging Material Specification"** as shown in **Annexure-III**.

6.3.1.5 Finished Product Specification shall be prepared as per format **"Finished Product Specification"** as shown in **Annexure-IV**.

6.3.1.6 Stability Study specification shall be prepared as per format **"Stability Study Specification"** as shown in **Annexure-V**.

6.3.1.7 Specification for Water shall be prepared as per format **"Specification of Water"** as shown in **Annexure-XIV**.

6.3.1.8 In case of Finished Product treated as a Packaging Material shall have Shelf Life and Retest Period (Ex.: SWFI Containers used in Injectable Facility).

6.3.1.9 Mention tests as specified in the monographs of IP / BP / USP / In-House as per requirement of RM, PM, in process, FP & ST to be tested with Reference to Drug License.

6.3.1.10 Fill up all the required details in the Specification Format as specified in the Official Monograph or as per the In-House Specification.

6.3.1.11 Provisional limits to be set up under the consultation with user department and final specification shall be made after performance of Three Batches.

6.3.2 STANDARD TEST PROCEDURE:

6.3.2.1 Standard Test Procedure can be divided into **Six** types as Raw Material, In–Process products, Packaging Material, Finished Product, Stability study, Water and General Test.

6.3.2.2 Raw Material Standard Test Procedure shall be prepared as per format **"Raw Material Standard Test Procedure"** as shown in **Annexure-VI.**

6.3.2.3 In-Process Standard Test Procedure shall be prepared as per format **"In-Process Standard Test Procedure"** as shown in **Annexure-VII**.

6.3.2.4 Packaging Material Standard Test procedure shall be prepared as per format **"Packaging Material Standard Test procedure"** as shown in **Annexure-VIII.**

6.3.2.5 Finished Product Standard Test procedure shall be prepared as per format **"Finished Product Standard Test Procedure"** as shown in **Annexure-IX.**

6.3.2.6 Generic Specific Product shall be prepared as per format **"Finished Product Standard Test Procedure"** as shown in **Annexure-IX**.

6.3.2.7 Stability Study Standard Test procedure shall be prepared as per format **"Stability Study Standard Test Procedure"** as shown in **Annexure-X.**

6.3.2.8 General Test Procedure shall be prepared as per format **"General Test Procedure"** as shown in **Annexure-XI.**

6.3.2.9 Water Standard Test procedure shall be prepared as per format **"Standard Test Procedure of Water"** as shown in **Annexure-XV.**

6.3.2.10 Describe tests as specified in the Monographs of IP / BP / USP / In-house as per requirement of all material to be tested.

6.3.2.11 Test must have the Acceptance Criteria.

6.3.2.12 Generic Name shall be written in both column of Product Name and Generic Name for Generic product specific STP. In Column of Ref. Spec. No. and Product Code "NA" shall be mentioned in case of generic product specific STP.

6.4 NUMBERING SYSTEM OF STANDARD TEST SPECIFICATION:

6.4.1 Each Specification shall have unique No. for identification and control. Once a number is assigned to any Specification, the same number shall not be assigned to any other Specification.

6.4.2 Each Specification No. shall consist of about 15 Alphanumeric Characters (Five Alphabets, eight Numeric and two Separators).

For Example: **STS/XX/NNNNNNNN**

Where,

First Three characters **STS** indicate the Standard Test Specification.

4th character is Slash **/** for Separator.

5th & **6th** character **XX** is represent code of Raw Material **RM**, In process **SF,** Packaging Material **PM, Finished** Product **FP**, Stability Study **ST.**

7th character is Slash **/** for Separator.

8th to 15th (08 Characters) Numerical characters **NNNNNNNN** represent Material / Product Code.

6.4.2.1 If Material / Product Code more or less than 8 characters then specification number shall be increase or decrease.

6.4.3 Specification for water sample shall be given about 13 Alphanumeric Characters.

For Example: **STS/QC/XX/NNN**

Where,

First Three characters **STS** indicate the Standard Test Specification.

4th character is Slash / for Separator.

5th & **6th** character QC is represent the Quality control

7th character is Slash / for Separator.

8th & **9th** is represent code of Purified water PW, Raw Water RW, if represent code more than two Characters than **8th** , **9th & 10th** character represent code i.e. Water for Injection WFI , Potable Water PPW and Pure Steam PSG.

10th character is Slash / for Separator.

11th ,12th & 13th Numerical characters **NNN** represent Serial Number i.e. 001

6.4.3.1 Follow below mentioned table for numbering system of Specification:

S. No.	Specification Name	Numbering system	Example
1.	Raw Material	STS/RM/Material Code	STS/RM/00000000
2.	In-Process Product	STS/SF/Material Code	STS/SF/00000000
3.	Packaging Material	STS/PM/Material Code	STS/PM/00000000
4.	Finished Product	STS/FP/Material Code	STS/FP/00000000
5.	Stability Study	STS/ST/Material Code	STS/ST/00000000
6.	Water	STS/QC/Code/Serial No.	STS/QC/PW/001

6.5 NUMBERING SYSTEM FOR SPECIFICATION (LOAN LICENSE PRODUCTS):

6.5.1 Each Specification shall have unique No. for identification and control. Once a number is assigned to any Specification, the same number shall not be assigned to any other Specification.

6.5.2 Each Specification No. shall consist of 16 Alphanumeric Characters (Five Alphabets, Nine Numeric and two Separators).

For Example: **STS/XX/NNNNNNNNN**

Where,

First Three characters **STS** indicate the Standard Test Specification.

4th character is Slash **/** for Separator.

5th & **6th** character **XX** is represent code of Raw Material **RM**, In-process Product **SF,** Packaging Material **PM,** Finished Product **FP** and Stability Study **ST.**

7th character is Slash **/** for Separator.

8th to 16th Numerical characters **NNNNNNNNN** represent Material / Product Code.

Follow below mentioned table for numbering system of Specification:

S. No.	Specification Name	Numbering system	Example
1.	Raw Material	STS/RM/Material Code	STS/RM/150000000
2.	In-Process Product	STS/SF/Material Code	STS/SF/180000000
3.	Packaging Material	STS/PM/Material Code	STS/PM/170000000
4.	Finished Product	STS/FP/Material Code	STS/FP/190000000
5.	Stability Study	STS/ST/Material Code	STS/ST/190000000

6.6 NUMBERING SYSTEM OF STANDARD TEST PROCEDURE:

6.6.1 Each STP shall have unique No. for identification and control. Once a number is assigned to any STP, the same number shall not be assigned to any other STP.

6.6.2 Each STP for Generic name/ Product name (Finished Product) Packaging Material, semi finish and Stability consist of 13 Alphanumeric Characters.

For Example: **STP/XX/QC/NNN**

Where,

First Three characters **STP** indicate the Standard Test Procedure.

4th character is Slash **/** for Separator.

5th & **6th** character **XX** is represent code of Packaging Material **PM,** Finished Product **FP, SF, Stability ST.**

7th character is Slash **/** for Separator.

8th to 9th QC character **QC** is Quality Control

10th character is Slash **/** for Separator.

11th to 13th Numerical characters **NNN** represent sequential number.

6.6.3 STP for Raw material consist of 10 Alphanumeric Characters.

For Example: **STP/XX/NNN**

Where,

First Three characters **STP** indicate the Standard Test Procedure.

4th character is Slash **/** for Separator.

5th & **6th** character **XX** is represent code of **RM**

7th character is Slash **/** for Separator.

8th to 10th Numerical characters **NNN** represent sequential number.

6.6.4 STP for Water consist of 10 Alphanumeric Characters .

For Example: **STP/QC/NNN**

Where,

First Three characters **STP** indicate the Standard Test Procedure.

4th character is Slash **/** for Separator.

5th & **6th** character **QC** is Quality Control

7th character is Slash **/** for Separator.

8th to 10th Numerical characters **NNN** represent sequential number.

6.6.4.1 Follow below mentioned table for numbering system of Standard test Procedure:

S. No.	Test Procedure Name	Numbering system	Example
1.	Raw Material	**STP/XX/** Sequential Number	STP/RM/001
2.	In-Process Product	STP/SF/QC/Sequential Number	STP/SF/QC/001
3.	Packaging Material	STP/PM/QC/Sequential Number	STP/PM/QC/001
4.	Finished Product	STP/FP/QC/Sequential Number	STP/FP/QC/001
5.	Stability Study	STP/ST/QC/Sequential Number	STP/ST/QC/001
6.	Water	STP/QC/Sequential Number	STP/QC/001

6.7 NUMBERING SYSTEM OF STANDARD TEST PROCEDURE (FOR LOAN LICENSE PRODUCTS):

6.7.1 For Loan license products, customer shall provide the Standard test procedure which shall be used as such. In case, if customer does not provide the STP, we shall follow the same format which used to prepare the Skymap STP as mentioned above.

6.8 NUMBERING SYSTEM OF GENERAL TEST PROCEDURE:

6.8.1 Each GTP shall have unique No. for identification and control. Once a number is assigned to any GTP, the same number shall not be assigned to any other GTP.

6.8.2 Each GTP No. shall consist of 09 Alphanumeric Characters (Three Alphabets, Five Numeric and One Separators).

For Example: GTP/NNNNN

Where,

First Three characters GTP indicate the General Test Procedure.

4th character is Slash / for Separator.

5th to 9th Numerical characters NNNNN represent sequential number of GTP.

6.9 PREPARATION OF MASTER, ISSUANCE, RETRIEVAL AND DESTRUCTION OF STANDARD TEST SPECIFICATION, STANDARD TEST PROCEDURE AND GENERAL TEST PROCEDURE:

6.9.1 After Approval by QA Department, STS, STP and GTP shall be stamped as **"MASTER COPY"** with Blue colour ink header (on all the pages) and sign and date with **Blue Ink Ball Point Pen**. Specimen of Master Copy stamp is shown in current version of SOP, Titled **"Documentation and Data Control"**.

6.9.2 Effective date shall be entered in all pages of header column **(Effective date :)** with **Blue Ink Ball Pen.**

6.9.3 After photocopying, Master STS, STP and GTP shall be stamped as **"CONTROLLED COPY"** with green colour stamp (all pages) and copy no., sign and date with **Black Ink Ball Point Pen** and Issuance shall be done as per format **"Issuance, Retrieval and Destruction Log For Standard Test Specification, Standard Test Procedure and General Test Procedure"** as shown in **Annexure-XII**.

6.9.4 Controlled Copy No. stamp shall be always at the right upper corner of the page with their respective Copy Number. Specimen of Controlled Copy stamp is shown in current version of as per SOP, Titled **"SOP FOR SOP"**.

6.9.5 In case, if any STS, STP and GTP is submitted to the external agencies (i.e. Regulatory, Customers / Partners etc.), shall be made "**UNCONTROLLED COPY"** and Issuance Record of Uncontrolled Copy shall be done as per SOP.

6.9.6 Previous version of Master Copy shall be made **"OBSOLETE COPY"** as per SOP.

6.9.7 Master Copy of STS, STP and GTP which is discontinued due to implementation of any new STS, STP and GTP shall be stamped **"DISCONTINUED COPY"** as per SOP, however the same STS No., STP No. and GTP No. shall not be allotted to any newly prepared STS, STP and GTP.

6.9.8 Distributed copy of STS, STP and GTP shall be retrieved to QA Department and destroyed by paper shredder and maintained in **"Issuance, Retrieval and Destruction Log for Standard Test Specification, Standard Test Procedure and General Test Procedure"** as shown in **Annexure-XII.**

6.9.9 Master Index of STS, STP and GTP shall be maintained by QA Department as per format **"Index of Standard Test Procedure / Specification for Raw Material / In-Process/Semi Finished Product / Packaging Material / Finished Product / Stability Study and General Test Procedure"** as shown in **Annexure-XIII.**

6.9.10 Index of STS, STP shall be updated in every Six months or whenever required, manual corrections shall not be allowed in this Index, and the Index shall be converted into protected PDF format with print option only.

6.10 REVISION OF STANDARD TEST SPECIFICATION, STANDARD TEST PROCEDURE AND GENERAL TEST PROCEDURE:

6.10.1 In the case of new STS, STP and GTP shall be made effective through Change Control Procedure and impact shall be evaluated.

6.10.2 Revision of STS, STP and GTP shall be done in-case of any updation in pharmacopeia or any other changes are required in the Specification and STP.

6.10.3 Any change required in the STS, STP and GTP, shall be performed through Change Control.

6.10.4 Discontinuation of any STS, STP and GTP shall be initiated by initiating Department through Change Control.

6.11 STORAGE OF STS, STP AND GTP (Master Copy / Soft Copy):

6.11.1 All Master Copy / Soft Copy of Approved STS, STP and GTP shall be retained in QA Department and Data Backup shall be kept in Information Technology (IT) Department.

6.12 ARCHIVAL AND DESTRUCTION OF MASTER STS, STP AND GTP:

6.12.1 All the Obsolete / Discontinued hard copy of Master STS, STP and GTP shall be scanned and retained in soft copy with back up facility for life cycle from the date of Obsolete / Discontinued and the hard copy shall be stored for **Five years.**

6.12.2 After five year, Obsolete / Discontinued STS, STP and GTP shall be destroyed through paper shredder and the destruction shall be done as per SOP.

7.0 ABBREVATION:

BP	British Pharmacopoeia
FP	Finished Product
GTP	General Test Procedure
IP	Indian Pharmacopoeia
Ltd.	Limited
No.	Number
PM	Packaging Material
PS	Physician Sample
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
Ref.	Reference
RM	Raw Material
SF	Semi Finished
SOP	Standard Operating Procedure
STP	Standard Test Procedure

STS	Standard Test Specification
USP	United States Pharmacopoeia

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Raw Material Specification	
Annexure-II	In-Process/Semi finished Product Specification	
Annexure-III	Packaging Material Specification	
Annexure-IV	Finished Product Specification	
Annexure-V	Stability Study Specification	
Annexure-VI	Raw Material Standard Test Procedure	
Annexure-VII	In-Process/Semi Finished Standard Test Procedure	
Annexure-VIII	Packaging Material Standard Test Procedure	
Annexure-IX	Finished Product Standard Test Procedure	
Annexure-X	Stability Study Standard Test Procedure	
Annexure-XI	General Test Procedure	
Annexure-XII	Issuance , Retrieval and Destruction Log for Standard Test Specification, Standard Test Procedure and General Test Procedure	
Annexure-XIII	Index of Standard Testing Procedure / Specification for Raw Material/In-Process/Semi Finished Product/Packaging Material /Finished Product/Stability Study and General Test Procedure	
Annexure-XIV	Specification of Water	
Annexure-XV	Standard Test Procedure of Water	

9.0 DISTRIBUTION:

- Controlled Copy No. 01 — Head Quality Assurance
- Controlled Copy No. 02 — Head Quality Control
- Master Copy — Quality Assurance Department

10.0 REFERENCES:

- D & C Acts & Rule.
- ICH Q6 "Specifications: Test Procedure and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances.

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-I
RAW MATERIAL SPECIFICATION

Department:			
TITLE:			
Specification No.:		**Item Code:**	
Revision No.		**Ref. STP No.:**	
Supersede No.:		**Review Date:**	
Effective Date:		**Page No.:**	
Retest Period:			

BODY:

S.No.	TEST	SPECIFICATION

REVISION HISTORY:

FOOTER:

---	Prepared By Officer/Executive QC	Checked By Manager QC	Approved By Head Quality Assurance
Name			
Signature			
Date			

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-II
IN-PROCESS/SEMI FINISHED PRODUCT SPECIFICATION

Department:			
TITLE:			
Specification No.:		**Item Code:**	
Revision No.		**Ref. STP No.:**	
Supersede No.:		**Shelf Life:**	
Effective Date:		**Review Date:**	
Retest Period:		**Page No.:**	

BODY:

S. No.	TEST	SPECIFICATION

REVISION HISTORY:

FOOTER:

---	Prepared By Officer/Executive QC	Checked By Manager QC	Approved By Head Quality Assurance
Name			
Signature			
Date			

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-III
PACKAGING MATERIAL SPECIFICATION

Department:			
TITLE:			
Specification No.:		**Item Code:**	
Revision No.		**Ref. STP No.:**	
Effective Date:		**Review Date:**	
Supersede No.:		**Page No.:**	

BODY:

S. No.	TEST	SPECIFICATION

REVISION HISTORY:

FOOTER:

---	Prepared By Officer/Executive QC	Checked By Manager QC	Approved By Head Quality Assurance
Name			
Signature			
Date			

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-IV
FINISHED PRODUCT SPECIFICATION

Department:			
TITLE:			
Specification No.:		**Item Code:**	
Revision No.		**Ref. STP No.:**	
Supersede No.:		**Shelf Life:**	
Effective Date:		**Review Date:**	
Retest Period:		**Page No.:**	

BODY:

S.No.	TEST	SPECIFICATION

REVISION HISTORY:

FOOTER:

---	Prepared By Officer/Executive QC	Checked By Manager QC	Approved By Head Quality Assurance
Name			
Signature			
Date			

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-V
STABILITY STUDY SPECIFICATION

Product Name:			
Generic Name:			
Specification No.:		**Item Code:**	
Revision No.		**Ref. STP No.:**	
Supersede No.:		**Shelf Life:**	
Effective Date:		**Review Date:**	
Retest Period:		**Page No.:**	

BODY:

S. No.	TEST	SPECIFICATION

FOOTER:

---	Prepared By Officer/Executive QC	Checked By Manager QC	Approved By Head Quality Assurance
Name			
Signature			
Date			

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-VI
RAW MATERIAL STANDARD TEST PROCEDURE

Department:			
TITLE:			
STP No.:		**Item Code:**	
Revision No.		**Ref. Specification No.:**	
Supersede No.:		**Review Date:**	
Effective Date:		**Page No.:**	
Retest Period:			

BODY:

1. Standard Test Procedure :

2. Sample Quantity Details:

S. No.	Test	Sample Quantity
1.	Quantity Required for Analysis (A)	
2.	Quantity Required for Control Sample (B)	
3.	Total Sample Quantity (A+B)	

REVISION HISTORY:

FOOTER:

---	Prepared By Officer/Executive QC	Checked By Manager QC	Approved By Head Quality Assurance
Name			
Signature			
Date			

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-VII
IN-PROCESS/SEMI FINISHED STANDARD TEST PROCEDURE

Department:			
TITLE:			
Ref. STP No.:		**Item Code:**	
Revision No.		**Specification No.:**	
Supersede No.:		**Shelf Life:**	
Effective Date:		**Review Date:**	
Retest Period:		**Page No.:**	

BODY:

1. **Standard Test Procedure :**
2. **Sample Quantity Details:**

S. No.	Test	Sample Quantity
1.	Quantity Required for Analysis	
Total Quantity Required for Analysis		

REVISION HISTORY:

FOOTER:

---	Prepared By Officer/Executive QC	Checked By Manager QC	Approved By Head Quality Assurance
Name			
Signature			
Date			

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-VIII
PACKAGING MATERIAL STANDARD TEST PROCEDURE

Department:			
TITLE:			
Ref. STP No.:		**Supersede No.:**	
Effective Date:		**Review Date :**	
Revision No.:		**Page No.:**	

BODY:

1. **Standard Test Procedure :**
2. **Sample Quantity Details:**

S. No.	Test	Sample Quantity
1.	Quantity Required for Analysis	

REVISION HISTORY:

FOOTER:

---	Prepared By Officer/Executive QC	Checked By Manager QC	Approved By Head Quality Assurance
Name			
Signature			
Date			

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-IX
FINISHED PRODUCT STANDARD TEST PROCEDURE

Department:			
TITLE:			
Ref. STP No.:		**Item Code:**	
Revision No.		**Specification No.:**	
Supersede No.:		**Shelf Life:**	
Effective Date:		**Review Date:**	
Retest Period:		**Page No.:**	

BODY:

1. **Standard Test Procedure :**
2. **Sample Quantity Details:**

S. No.	Test	Sample Quantity
1.	Quantity Required for Analysis	
2.	Quantity Required for Control Sample	
Total Sample Quantity		

REVISION HISTORY:

FOOTER:

---	Prepared By Officer/Executive QC	Checked By Manager QC	Approved By Head Quality Assurance
Name			
Signature			
Date			

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-X
STABILITY STUDY STANDARD TEST PROCEDURE

Product Name:			
Generic Name:			
Ref. STP No.:		**Item Code:**	
Revision No.		**Specification No.:**	
Supersede No.:		**Shelf Life:**	
Effective Date:		**Review Date:**	
Retest Period:		**Page No.:**	

BODY:

1. **Standard Test Procedure :**
2. **Sample Quantity Details:**

S. No.	Test	Sample Quantity
1.	Quantity Required for Analysis	

REVISIONHISTORY:

FOOTER:

---	Prepared By Officer/Executive QC	Checked By Manager QC	Approved By Head Quality Assurance
Name			
Signature			
Date			

ANNEXURE-XI
GENERAL TEST PROCEDURE

General Test Procedure For :			
GTP No.:		**Revision No.**	
Effective Date:		**Superseded Revision No.:**	
Review Date:		**Page No.:**	

BODY:

GENERAL TEST PROCEDURE:

REVISION HISTORY:

FOOTER:

---	**Prepared By Officer/Executive QC**	**Checked By Manager QC**	**Approved By Head Quality Assurance**
Name			
Signature			
Date			

ANNEXURE-XII
ISSUANCE, RETRIEVAL AND DESTRUCTION LOG STS, STP & GTP

S. No.	Issuance								Retrieval			Destruction		Remarks
	Product / Material Name/ GTP for	Stage#	STS / STP/ GTP	STS No./ STP No./ GTP No.	Department	Copy No.	Issued By (Sign & Date)	Received By (Sign & Date)	No. of Copies Retrieved	Retrieved By (Sign & Date)	Received By (Sign & Date)	Destroyed By (Sign & Date)	Checked By (Sign & Date)	

Stage represents RM/SF/PM/FP/Shelf Life

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-XIII
INDEX OF STS, STP & GTP

HEADER:

BODY:

S. No.	Product / Material Name/ General Test Procedure For	Stage	STS No. / STP No./ GTP No.	Revision No.	Effective Date

FOOTER:

---	Prepared By Officer/Executive QC	Checked By Manager QC	Approved By Head Quality Assurance
Name			
Signature			
Date			

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE- XIV
WATER SPECIFICATION

Department:			
TITLE:			
STS No.		**Revision No.**	
Effective Date		**Review Date**	
Supersede No.		**Ref. STP No.**	
		Page No.	

BODY:

S.No.	TEST	SPECIFICATION

REVISION HISTORY:

FOOTER:

---	Prepared By Officer/Executive QC	Checked By Manager QC	Approved By Head Quality Assurance
Name			
Signature			
Date			

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Approval, Control, Issuance, Revision, Retrieval and Destruction of Standard Test Specification, Standard Test Procedure and General Test Procedure	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE- XV
STANDARD TEST PROCEDURE OF WATER

Department:			
TITLE:			
Ref. STP No.		**Revision No.**	
Supersede No.		**Effective Date**	
Specification No.		**Review Date**	
		Page No.	

BODY:

1. Standard Test Procedure:

2. Sample Quantity Details:

S. No.	TEST	SAMPLE QUANTITY
1.	Quantity Required for Analysis	

REVISION HISTORY:

FOOTER:

---	Prepared By Officer/Executive QC	Checked By Manager QC	Approved By Head Quality Assurance
Name			
Signature			
Date			