1.0 OBJECTIVE:

To lay down a Procedure for Preparation, Approval, Control, Distribution, Revision, Retrieval and Destruction of Standard Operating Procedure.

2.0 SCOPE:

This SOP is applicable to all the manufacturing sites.

3.0 RESPONSIBILITY:

QA (Officer/Executive): Preparation, Review, Distribution, Revision, Retrieval and Destruction of this SOP.

QA (Head/Designee): Review, Approval, Training and effective implementation of this SOP.

QA (Officer/Executive): Preparation, Distribution, Revision, Retrieval, Effective implementation and Destruction of QA SOP's.

Respective Departments (Officer/Executive): Preparation of SOP's.

Respective Departments (Head/Designee): Review and Training of SOP's.

4.0 ACCOUNTABILITY:

Head QA: Approval, Ensure Training and Implementation of QA SOP's.

Respective Departments (Head/ Designee): (except QA SOP's): Review, Ensure Training and Implementation of Respective SOP's.

5.0 DEFINITION: Not Applicable

6.0 PROCEDURE:

Note: *To make SOP user friendly, better understandable and to ensure full compliance, if there is a need to demonstrate then Diagrams, Flow Charts, Decision Trees and Pictures shall be considered as a part of the SOP.*

6.1 RESPONSIBILITY:

A person or group of personnel performing /conducting a task or activity.

6.1.1 **Accountability:** A person, who is responsible to ensure that a task is conducted or performed as per Procedure.

6.2 GENERAL INSTRUCTIONS:

6.2.1 All SOP's shall be written in English language by Using Microsoft word.

6.2.2 The language shall be simple and easy to understand.

6.2.3 No abbreviations shall be used in the Title of the SOP.

6.2.4 All SOP's shall have clear and meaningful Title.

6.2.5 In case, the users are not able to write, read, speak or understand English then SOP shall be translated into vernacular language e.g. Hindi. using font style "krutiDev 011" & font size 12"

6.2.6 English version (mother SOP) and translated Hindi version procedure SOP shall be displayed side by side.

6.3 DESIGN OF SOP:

6.3.1 **SOP Format:**

6.3.2 All SOP's shall contain Header, Footer and Body prepared in format **"SOP Format (Specimen Copy)"** as per **Annexure-I**.

6.3.2.1 All pages shall contain Name, Signature and Date in column provided in Footer part.

6.3.2.2 Master Copy of SOP's shall be printed on **A4 size** using **"Times New Roman"** Font size 12 with black Ink.

Note: *In case of colour print out required in SOP's for e.g.* Stamps Specimen, Utility *Pipelines, Status Label etc., colour print of specific page shall be taken and made as master and shall be coloured scanned, printed and controlled for distribution to plant.*

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

6.3.2.4 Paper shall have Width 8.5", Height 11" or 11.5" (Paper Size Custom) and Margin Top2" Left1" Right0.4"and Bottom Margin2".

6.3.2.5 All the points in the SOP shall be numbered sequentially and sub paragraph of the SOP shall be also numbered sequentially with an incremental number derived from the heading number. (E.g. for Procedure 6.1, 6.1.1, 6.1.1.1, ……..)

6.3.2.6 All SOP contents shall be covered by Single Borderline (Line width ½ pt).

6.3.3 **LINE SPACING:**

6.3.3.1 The Line Spacing between two points or title and subtitle shall be 1.5 and the fonts shall be “**Times New Roman”,** Font Size 12.

6.3.4 **FONT SIZE OF HEADER, FOOTER AND BODY CONTENTS:**

NAME OF CONTENT	FONT SIZE
HEADER:	
Name of the Organization and Location	16 Bold and Capital
Logo (On Left Hand Side Corner of The Page)	**……………:**Height-0.75’’and Width- 0.63”
Restricted Circulation	08 Normal and Bold
Standard Operating Procedure	12 Bold and Capital
Title of SOP	12 Bold and Capital
SOP No. (Heading)	12 Running and Bold
Revision No. (Heading)	12 Running and Bold
Supersedes Revision No. (Heading)	12 Running and Bold
Department (Heading)	12 Running and Bold
Effective Date (Heading)	12 Running and Bold
Revision Date (Heading)	12 Running and Bold
Page No.(Heading)	12 Running and Bold
Row height	0.2”
FOOTER:	
Prepared By, Checked By, Approved By	12 Running and Bold
Name, Signature and Date	12 Running and Bold

NAME OF CONTENT	**FONT SIZE**
Row height	0.4”
Format No.	10 Capital and Normal
BODY:	12 Capital and Bold
Paragraph Main Heading	12 Running and Bold
Subheading	12 Running and Bold

6.3.5 **CONTENT OF HEADER:**

6.3.5.1 Header:

6.3.5.1.1 Header of SOP shall have the Name of Organization (Including Name of Location). Header shall have the **“Logo”** of Organization in Left corner on top, and Restricted Circulation on right corner in 8 font size, followed by “**STANDARD OPERATING PROCEDURE**” in center written in Bold and Capital letter with 12 font size as per **Annexure-I.**

6.3.5.2 Title:

6.3.5.2.1 “**TITLE”** of the SOP shall be written in “**Times New Roman”,** bold and capital letter with Font size 12 Capital

6.3.5.3 SOP No. (Numbering System of SOP’s)

6.3.5.3.1 Each SOP shall be allocated an unique number, once a number is allotted to any SOP; the same number shall not be assigned to any other SOP.

6.3.5.3.2 All SOP’s Numbers shall contain TEN Alphanumeric Characters (Five Alphabets, Two Separator and Three Numerical characters (e.g. SOP/QA/001).

6.3.5.3.3 For different Department coding shall be given as below for example: SOP/XX/001

SOP is Standard Operating Procedure

XX – Indicates Department Code

001 – Indicates Serial No.

6.3.5.4 Effective Date:

6.3.5.4.1 Effective Date shall be entered in the form of DD/MM/YYYY.

6.3.5.4.2 For Example: 02/06/2020

6.3.5.4.3 This effective date represents that SOP shall be implemented from this date after training and shall be made effective within 10 working days.

6.3.5.4.4 Upon completion of training, Effective date shall be entered in respective column (Effective date with blue colour ink ball pen.

6.3.5.5 Revision Date:

6.3.5.5.1 The periodic review shall be **Two Years** from the effective date of the SOP.

For Example: If the SOP having effective date **“02/06/2020”** its next revision Date shall be **“01/06/2022”**.

6.3.5.5.2 Upon completion of training, Revision date shall be entered in respective column (Revision date with blue colour ink ball pen.

6.3.5.6 Page No.:

6.3.5.6.1 The Page Number shall be mentioned in ‘X of Y’ format.

For Example: If SOP contains 30 pages then the first page number of the SOP shall be 1 of 30 and the second page number shall be 2 of 30 respectively.

6.3.5.7 Space for Stamping:

6.3.5.7.1 **“MASTER COPY”** stamp in empty space in the upper Header part on the right hand side of the Header.

6.3.6 **CONTENT OF FOOTER:**

6.3.6.1 Footer:

6.3.6.1.1 Footer shall contain the following headings:

6.3.6.2 Prepared By:

6.3.6.2.1 Officer / Executive who initiates/ prepares the SOP shall sign off along with Date and Name in capital letters.

6.3.6.3 Checked By:

6.3.6.3.1 Concerned Department Head shall check and sign along with date and name in capital letters.

6.3.6.4 Approved By:

6.3.6.4.1 SOP's of all departments in plant shall be Approved by QA Head and signed off along with Date and Name in capital letters.

6.3.6.5 Format No.:

6.3.6.5.1 Format No. shall be mentioned in font size 10, Normal and Capital letters.

6.3.6.5.2 Format No. shall be mentioned in the bottom left hand side corner of the page after Footer and outside the page border as SOP/QA/001/F01 with revision No. on all pages of the SOP.

6.3.6.6 Name:

6.3.6.6.1 Full Name of person shall be written, who signs the SOP in Capital Letters.

6.3.6.6.2 All Signatures, Date, Name on Master Copy shall be written by person with Blue Ink Ball Point Pen.

6.3.6.7 Signature:

6.3.6.7.1 Signature shall be done by a person in the SOP as per "Specimen Signature Record".

6.3.6.8 Date:

6.3.6.8.1 Date shall be in the form of **DD/MM/YYYY** (Date/Month/Year).

6.3.7 **CONTENTS OF BODY (SOP):**

6.3.7.1 All SOP's shall be prepared by using following contents:

1. Objective
2. Scope
3. Responsibility
4. Accountability
5. Definition
6. Procedure
7. Abbreviations
8. Annexure
9. Distribution
10. References
11. Revision History

6.3.7.2 Objective:

6.3.7.2.1 The objective of the SOP shall be written in short, clear and meaningful. The objective of all SOP's shall be started with **"To lay down".**

6.3.7.3 Scope:

6.3.7.3.1 This Section defines the applicability of the SOP and also specifies Departments, location in which this SOP shall be applicable. The scope of all SOP's shall be started with **"This SOP is applicable".**

6.3.7.4 Responsibility:

6.3.7.4.1 Department/ concerned person shall be responsible who are directly/ indirectly involved in the activity.

6.3.7.5 Accountability:

6.3.7.5.1 For all Plant specifics SOP's, Head QA shall be accountable for the activity.

6.3.7.6 Definition:

6.3.7.6.1 **Standard operating procedure. :**established or prescribed methods to be followed routinely for the performance of designated operations or in designated situations called also standing operating procedure.

6.3.7.7 Procedure:

6.3.7.7.1 Procedure / Method shall be written in precise, adequate and in short sentences. Do not write the instructions in long paragraphs, subheading shall be given, if required.

6.3.7.8 Abbreviations:

6.3.7.8.1 All abbreviations used in a SOP shall be defined or explained (e.g. **SOP: Standard Operating Procedure**).

6.3.7.9 Annexure:

6.3.7.9.1 Enclose all the Annexure with SOP if applicable and also mention a list of all Annexure enclosed in the SOP. If there is no Annexure in the SOP, mention ‘Not Applicable’ (NA) under this subheading.

6.3.7.9.2 New Format/ annexure shall be made as per format “Making New Format (For Annexure)” as shown in Annexure-II.

6.3.7.9.3 All Formats of the SOP shall be part of SOP as “Annexure”.

6.3.7.9.4 Each Annexure shall be numbered sequentially by Roman Numbering System.

6.3.7.9.5 First Annexure of any particular SOP shall be numbered as “Annexure-I”.

6.3.7.9.6 Each Annexure shall have unique Format Number which contains Header, Body and Footer. Font size of Annexure contents is mentioned below:

6.3.7.10 FONT SIZE DETAILS OF ANNEXURE CONTENT

CONTENT OF ANNEXURE	FONT SIZE
HEADER:	
Numbering of the Annexure	12 Capital & Bold (Capital letter)
Logo on the Left Hand Corner of the Annexure	**…………….:** Height-0.75’’& Width-0.63’’
Name of Organization and Location	14 Capital & Bold
Department Name (If Required)	12 Capital & Bold
Title of Annexure	12 Capital & Bold
Row height	0.3”
FOOTER:	
Prepared By, Checked By, Approved By	12 Running and Bold
Name, Signature and Date	12 Running and Bold
Row height	0.4”
Format No.	10 Capital and Normal

6.3.7.11 Numbering System of Formats:

6.3.7.11.1 Each Format shall be assigned unique Format Number for identification and control. Once a Number is allocated to any Format; the same number shall not be repeated to any other format.

6.3.7.11.2 Each Format No. shall consist of Seventeen Alphanumeric Characters (Six Alphabets, Three Slash Separator and Five Numerical characters (e.g. SOP/QA/001/F01-00) and one dash separator.

For Example: First format No. for QA SOP No. **SOP/QA/001** shall be numbered as SOP/QA/001/F01-00.

Where,

First Three characters indicate the SOP.

4th character is Slash / for Separator.

5th& 6th character indicates Department code.

7th character is Slash / for Separator.

8th, 9th and 10th Numerical characters 001 indicate Serial Number of the SOP.

11th character is Slash / for Separator

12th, 13th and 14th character Indicates Format No.

15th - is Dash

16th and 17th Numerical characters indicate Revision Number of that particular format which starts with 00 and there shall be increment of One Digit after every revision.

6.3.7.11.3 Actual recording can be made in the form of:

1. Duplicate / Triplicate Books / Bound Books
2. Ledgers
3. Computer Printouts
4. Registers
5. Pre Printed Forms

6.3.7.11.4 All Register / Duplicate / Triplicate Book / Computer Printouts / Ledgers / Pre Printed forms shall have Format No. on left lower corner same as Format No. of Annexure in SOP.

6.3.7.11.5 In case of Bound Book (Registers, Log Books and Ledgers) of Annexure / Formats the Formats Register Pages shall have the page numbering system. Followed by XXX pattern (e.g. 001, 002,……..)

6.3.7.11.6 All the Annexure relevant to the SOP’s shall be attached as a part of specimen, and its reference shall be mentioned in the SOP.

6.3.7.12 Revision of Formats and Annexure:

6.3.7.12.1 Any changes in the Format shall be handled through Change Control SOP.

6.3.7.12.2 If there is a change in format, then SOP shall be revise accordingly.

6.3.7.12.3 If there is change in the content of SOP, having impact in the format then format shall be revised with change in revision number of format.

6.3.7.12.4 If there is change in content of SOP, having no impact in the format then revision number of SOP shall be change and revision number of format shall remains the same.

6.3.7.12.5 QA Department shall retrieve all the obsolete Formats and shall replace with the current version.

6.3.7.12.6 In case, addition of new Annexure / Format, same shall be numbered sequentially.

6.3.7.13 Discontinuation of Any Format in SOP:

6.3.7.13.1 In case of Discontinuation of any format of SOP it shall be written in Annexure table under Format No. column as **"Format is Discontinued"**

6.3.7.13.2 QA shall retrieve all the Controlled Copy of Discontinued Formats of respective Department at the plant and destroy with the help of paper shredder/manually. The details of destruction shall be recorded in the as per Format **"Master/Executed Document Destruction Record"** as per **Annexure-VIII of** SOP (Procedure for Documentation & Data Control).

6.3.7.14 Distribution:

6.3.7.14.1 All SOP's shall be distributed as per SOP's distribution list.

6.3.7.15 References:

6.3.7.15.1 All references and/ or any guidance documents used to prepare the SOP shall be mentioned.

6.3.7.15.2 In case, there is no reference used for the SOP, mention as **'Not Applicable (NA)'.**

6.3.7.16 Revision History:

6.3.7.16.1 Any Change / Revision in the SOP shall be updated and mention in Change History Log with Revision No., Change Control No., Detail of changes, Reason for changes, Effective date and Done by.

6.3.7.16.2 Specimen of Change History Log is as below:

Revision No.	Change Control No.	Detail of Changes	Reason for Change	Effective Date	Done By

6.4 PREPARATION OF SOP:

6.4.1 QA shall provide the Specimen copy as per format **"SOP Format (Specimen Copy)"** as shown in **Annexure-I** of SOP to the respective Department to prepare the SOP.

6.4.2 The person performing the activity of respective department shall prepare the SOP.

6.4.3 "Initiated by/ prepared by" shall provide the Soft copy of SOP to the reviewer as PDF Format with watermark as "DRAFT".

6.4.4 The reviewer shall check the draft SOP for accuracy, adequacy, completeness and correctness.

6.4.5 "Initiated by/ prepared by" shall incorporate all the comments and suggestions of reviewer and departmental Head in draft SOP.

6.4.6 Final draft soft copy shall be provided to QA by all the departments at the plant.

6.4.7 QA shall take the printout of all SOP for signature.

6.4.8 Print out of SOP shall be provided to User Departments for signature i.e. Prepared by, Checked by.

6.4.9 Upon signature of Checked By, signed off SOP shall be sent back to QA for Approval and Distribution.

6.4.10 Soft Copy of all final SOP's prepared by the User Department shall be transferred to QA and shall be deleted in presence of QA person.

6.4.11 After signed off, training shall be imparted on the SOP and further SOP shall be made effective.

6.4.12 Upon Approval all master copy shall be stamped as **"MASTER COPY"** with Blue colour ink (all pages) and sign and date with in Blue Ink Ball Point Pen.

6.4.13 Specimen of Master Copy stamp in Annexure VI.

6.5 STORAGE OF SOP (Master Copy / Soft Copy):

6.5.1 All Master Copy shall be printed in QA Department only and soft copy of Approved SOP's shall be stored in QA Department, data backup shall be kept in Information Technology (IT) Department.

6.6 TRAINING OF SOP's:

6.6.1 Training of QA SOP's shall be imparted by Head QA / Designee to QA personnel.

6.6.2 Training of other SOP's shall be imparted by concerned Department Head / Designee to concern personnel.

6.6.3 Each department shall be responsible to provide the training on departmental SOP's and maintain the records in their respective departments.

6.6.4 Training shall be imparted by Head QA/ Designee, Concerned Department Head/ Designee to respective personnel for effective implementation of the SOP's.

6.6.5 Post training, SOP shall be made effective within 10 working days.

6.6.6 After training of SOP, the training shall be recorded in **"Training Attendance Record"** as per **QA SOP "Training of Personnel"** and one copy shall be enclosed with the SOP.

6.7 CONTROL, ISSUANCE, DISTRIBUTION AND RETRIEVAL OF SOP's:

6.7.1 For distribution of all SOP's, QA shall take the Photocopy of Master SOP's.

6.7.2 After photocopying of master copy shall be stamped as **"CONTROLLED COPY"** with green colour stamp (all pages) and Copy No., sign and date with **Black Ink Ball Point Pen**. Mention Copy No. as per Point No. 6.7.7 list of copy number for distribution of SOP's

6.7.3 Specimen of Controlled Copy No. stamp in Annexure VI.

6.7.4 If any additional copy of SOP is requested by any department, SOP shall be issued as per Format **"Request Form for Issuance of SOP"** as shown in **Annexure-IV.**

6.7.5 Photocopying of Controlled copy of SOP is prohibited.

6.7.6 All SOP's shall be distributed by QA to respective departments. Distribution record shall be maintained by QA as per Format **"SOP Issuance, Retrieval & Destruction Log"** as shown in **Annexure-III.**

6.7.7 Distribution copies of SOP's shall be distributed as per below (Specimen list), but not limited to.

LIST OF COPY NUMBER FOR DISTRIBUTION OF QA SOP's (SPECIMEN) Sr. No.	COPY NUMBER	DEPARTMENT
1.	Controlled Copy No.01	Quality Assurance Department

6.7.8 Revised SOP shall be distributed only after retrieval copy of Supersede SOP.

6.7.9 The distribution of all the SOP's shall be carried out by QA only.

6.7.10 Department wise Master List of all SOP's shall be maintained by QA as per format **"Index of Standard Operating Procedure"** as shown in **Annexure-V.**

6.7.11 The list of SOP's shall be updated twice in a year or as and when required.

6.7.12 If the SOP is discontinued, the same SOP No. shall not be allotted to any other SOP.

6.7.13 SOP Number shall not be removed from SOP Index and mention "SOP Discontinued" in the Remarks column of Index of Standard Operating Procedure.

6.7.14 QA Officer / Executive shall be responsible for retrieval of the previous version of SOP's before issuing revised copy.

6.7.15 All retrieved controlled / display copies shall be collected by QA Department and record as per format **"SOP Issuance, Retrieval & Destruction Log"** as shown in **Annexure-III** and destroyed by Paper Shredding Machine.

6.8 PREPARATION OF MASTER, CONTROL AND DISTRIBUTION OF FORMATS/ ANNEXURES:

6.8.1 All the formats shall be prepared from the soft copy of master SOP. Printout of formats shall be taken and all the pages shall be stamped as **"MASTER COPY"** and signed off by using **Blue ink ball point pen.**

6.8.2 For distribution of all Formats, QA shall issue Master Formats after photocopying along with controlled copy stamp to respective department and issuance, retrieval & destruction record shall be maintained as per Format No. ……titled **"Formats Issuance, Retrieval & Destruction Log".** For details refer SOP titled **"Procedure for Documentation & Data Control"**

6.8.3 For distribution of all plant QA and other department Formats, plant QA shall issue the controlled copy of Formats to all respective departments.

6.8.4 All the annexure as specimen copy for SOP's shall be provided by QA and respective department to prepare the SOP Format through MS Office.

6.8.5 Computer Generated Format shall have same Format No. as mentioned in Annexure / Format of SOP and shall not have controlled copy stamp.

6.8.6 **CONTROLLED COPY STAMP:**

6.8.6.1 Photocopy of all master formats shall be stamped as **'CONTROLLED COPY'** in Green ink at right corner of the all pages below master stamp and shall be signed by **Black Ink Ball Point Pen**.

6.8.6.2 Formats shall have **"Controlled Copy Stamp"** only.

6.8.6.3 Master Copy of SOP shall be photocopied and stamped as **'CONTROLLED COPY'** containing Copy No., Sign & Date in Green ink in the right upper corner of the page and shall be signed by **Black Ink Ball Point Pen**.

6.8.6.4 Specimen of Controlled Copy stamp in **Annexure VI.**

6.8.7 **DISPLAY COPY STAMP:**

6.8.7.1 After **'CONTROLLED COPY'** stamp SOP issued for display purpose shall be stamped as **'DISPLAY COPY'** in Violet ink on bottom right corner.

6.8.7.2 Specimen of Display Copy stamp is presented in A**nnexure VI.**

6.8.8 **UNCONTROLLED COPY STAMP:**

6.8.8.1 Any SOP required to submit to the external agencies (i.e. Regulatory, Customers / Partners etc.) a photocopy of master copy shall be made by QA and all pages shall be stamped as **"UNCONTROLLED COPY"** in Red Ink on bottom left corner of the page and shall be signed by **Black Ink Ball Point Pen.**

6.8.8.2 SOP shall be copied by authorized person only.

6.8.8.3 Specimen of Uncontrolled Copy stamp in A**nnexure VI.**

6.8.9 **OBSOLETE COPY STAMP:**

6.8.9.1 Revision of SOP shall be done through Change Control Procedure and supersede version of Master Copy shall be stamped as '**OBSOLETE COPY'** in Red Ink in the Middle of all the pages, and shall be signed by **Black Ink Ball Point Pen.**

6.8.9.2 Specimen of Obsolete Copy stamp in **Annexure VI.**

6.8.10 **DISCONTINUED COPY STAMP:**

6.8.10.1 Master Copy of SOP which is discontinued due to implementation of any new documents shall be stamped as **'DISCONTINUED COPY** in Red Ink at the middle of all the pages and shall be signed by **Black Ink Ball Point Pen.**

6.8.10.2 The specimen of **Discontinued Copy** stamp in **Annexure VI.**

6.8.10.3 Stamps shall be used as per format "**Stamps Location for SOP's (Specimen Copy)"** as shown in **Annexure-VI.**

6.8.11 **ADDITIONAL PAGE STAMP:**

6.8.11.1 Additional pages shall be stamped as **'ADDITIONAL PAGE'** in violet ink at Footer in center and shall be signed by **Black Ink Ball Point Pen** with Controlled Copy stamp at predefined place.

6.8.12 **REVIEWED STAMP:**

6.8.12.1 Any Reference documents from outside Agency received at QA, shall be reviewed and stamped with **"REVIEWED"** on last page at centre of footer of the document in Violet ink and shall be signed by reviewer by **Black Ink Ball Point Pen.**

6.8.13 **REFERENCE COPY STAMP:**

6.8.13.1 When multiple copies of any executed document (i.e. filled deviation, Incident, Change Control, training record, batch conversion note etc.) are required for filing with other documents as reference, **"REFERENCE COPY"** stamp in violet ink shall be put above header in centre and shall be signed by **Black Ink Ball Point Pen**.

6.8.14 **APPROVED BY STAMP:**

6.8.14.1 Any Reference documents from outside Agency like calibration certificates, shade card, artworks which required QA Approval shall be stamped as **"APPROVED BY"** in Green ink on non-text part of the page.

6.9 REVISION OF SOP:

6.9.1 The review period shall be **Two Years** from the effective date of the SOP. Periodic review of the SOP shall be initiated through change control.

6.9.2 If any change is required in the SOP, same can be done at any time during the period after due approval of Change Control.

6.9.3 In case, the proposed change(s) is/are not justified when reviewed, same shall be disapproved by Head QA / Designee.

6.9.4 Revised SOP shall have next Revision No. and change(s) made in SOP shall be recorded in Change History Log.

6.9.5 At the end of two years, the SOP shall be reviewed by respective department

6.9.6 The respective Department initiating the change in the SOP's shall submit the Change control, Training Records and/or the supportive data to QA Department.

6.9.7 For discontinuation of any SOP mention "SOP Discontinued" in the remarks column of Index of Standard Operating Procedure.

6.10 ARCHIVAL AND DESTRUCTION OF MASTER SOP's:

6.10.1 All the Obsolete / Discontinued hard copy of Master SOP's shall be scanned and retained in soft copy with back up facility for life cycle from the date of Obsolete / Discontinued of SOP. Hard copy of Plant specific SOP's shall be stored only for 2 years from the date of Obsolete / Discontinued SOP and Destruction shall be done as per format **"Master SOP Destruction Record"** as shown in **Annexure-VIII.**

7.0 ABBREVIATIONS:

EHS : Environment, Health & Safety
NA : Not Applicable
No. : Number
PDF : Portable Document Format
QA : Quality Assurance
QC : Quality Control
Sign : Signature
SOP : Standard Operating Procedure

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	SOP Format (Specimen Copy)	……………
Annexure-II	Making New Format	…………
Annexure-III	SOP Issuance, Retrieval & Destruction Log	…………

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-IV	Request Form for Issuance of SOP	……………
Annexure-V	Index of Standard Operating Procedure	……………..
Annexure-VI	Stamps Location For SOP's (Specimen Copy)	…………….
Annexure-VII	Issuance Record of Uncontrolled Copy	…………….
Annexure-VIII	Master SOP's Destruction Record	……………

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01 Quality Assurance Department
- Controlled Copy No. 02 Quality Control Department
- Controlled Copy No. 03 Production Department
- Controlled Copy No.04 Human Resource Department(HR)
- Controlled Copy No. 05 Engineering Department
- Controlled Copy No. 06 Warehouse Department(Store)
- Controlled Copy No. 07 Information Technology Department
- Controlled Copy No. 08 Purchase Department

10.0 REFERENCES:

- US Code of Federal Regulations, Current Good Manufacturing Practice for Finished Pharmaceuticals (21 CFR -Part 211), Food and Drug Administration, 21 CFR, Chapter-I.
- A WHO Guide to Good Manufacturing Practice (GMP) Requirements, Part–I, Standard Operating Procedures and Master Formulae, WHO/VSQ/97.01 Quality Assurance of Pharmaceuticals, 2nd Edition, Volume- 2, 2007.

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		

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

Logo

ANNEXURE–I

SOP FORMAT (SPECIMEN COPY)

STANDARD OPERATING PROCEDURE

HEADER OF SOP:

Restricted Circulation

Department:			
TITLE :			
SOP No.		**Revision No.**	
Effective Date		**Supersedes**	
Review Date		**Page No.**	

FOOTER OF SOP:

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

FORMAT No.: …………….

Page X of Y

ANNEXURE–II

HEADER OF FORMAT:

Logo	***X**
	DEPARTMENT
	TITLE

BODY OF FORMAT:

TABLE OF CONTENT

FOOTER OF FORMAT:

FORMAT No.:…………. Page X of Y

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

ANNEXURE-III

SOP ISSUANCE, RETRIEVAL & DESTRUCTION LOG

Title of SOP: **SOP No.:** **Revision No.:**

ISSUANCE						RETRIEVAL OF SUPERSEDE VERSION		DESTRUCTION
Issued to Department	**Total Controlled Copy issued**	**File Controlled Copy**	**No. of Display Copy issued**	**Issued By (Sign &Date)**	**Received By (Sign &Date)**	**Retrieved By (Sign & Date)**	**Received By (Sign & Date)**	**Destroyed By (Sign & Date)**

ANNEXURE-IV

REQUEST FORM FOR ISSUANCE OF SOP

To, **Date:**

The QA

From:

S.No.	SOP Title	SOP No.	Revision No.	No. of Copies Required	Reason for Issuance

Checked By
Head of the Department
Sign & Date

Approved By
Head QA/Designee
Sign & Date

ANNEXURE-V

INDEX OF STANDARD OPERATING PROCEDURE

Effective Date: **Revision No:**

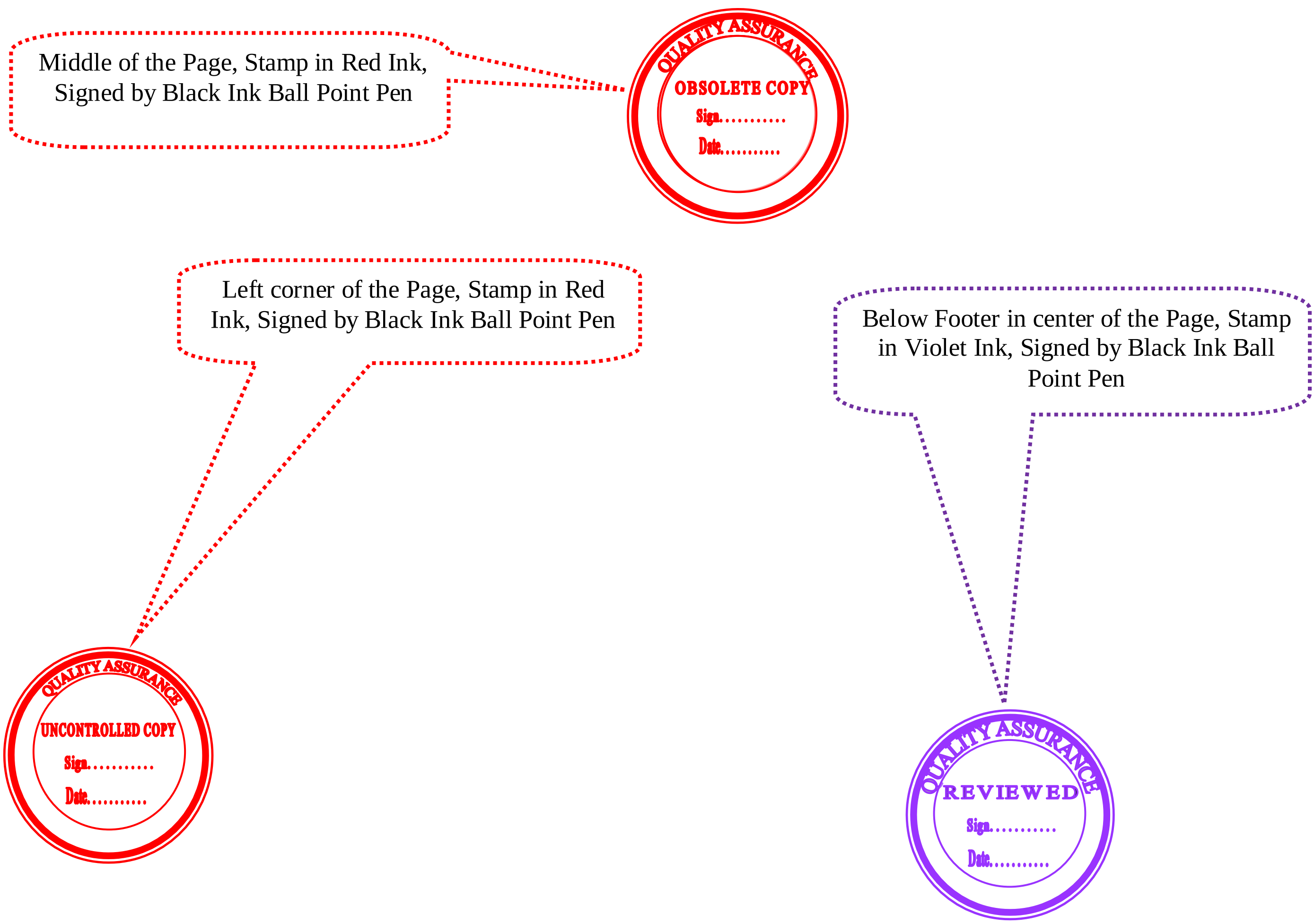
S.No.	SOP Title	SOP No.	Revision No.	Effective Date	Review Date	Remarks

Prepared by
Sign/Date

Checked by
Sign/Date

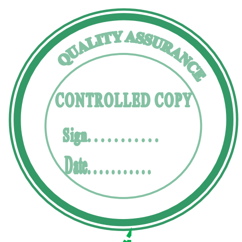
ANNEXURE – VI

STAMPS LOCATION FOR SOP's (SPECIMEN COPY)



Middle of the Page, above header, Stamp in Violet Ink, Signed by Black Ink Ball Point Pen

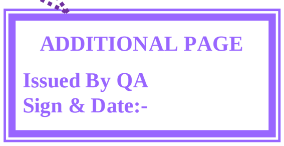
Right Upper Corner of the Page, Stamp in Blue Ink, Signed by Blue Ink Ball Point



Middle of the Page, Stamp in Red Ink, Signed by Black Ink Ball Point Pen

Below Right Upper Corner of the Page, Stamp in Green Ink, Signed by Black Ink Ball Point

Below Footer in center of the Page, Stamp in Violet Ink, Signed by Black Ink Ball Point Pen



Right Corner of the Page, Stamp in Violet Ink

Below Right Upper Corner of the Page, Stamp in Green Ink, Signed by Black Ink Ball Point Pen

On Non-text part of the Page, Stamp in Green Ink, Signed by Black Ink Ball Point Pen

ANNEXURE – VII

ISSUANCE RECORD OF UNCONTROLLED COPY

Month/Year:

S.No.	Date	Document Title	Document No.	Purpose	Issued By	Issued To	Remarks

ANNEXURE –VIII

MASTER SOP's DESTRUCTION RECORD

S.No.	Document Title	SOP No.	Date of Destruction	Destruction Done By (Sign & Date)	Destruction Checked By (Sign & Date)	Remarks