STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Procedure for Documentation and Data Control	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a Procedure for Documentation and Data Control.

2.0 SCOPE:

This SOP is applicable to Documentation and Data Control for all Department of ……

3.0 RESPONSIBILITY:

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

QA Manager: Review, Training and effective implementation of this SOP to all concerned Departments.

Respective Departments: Preparation and Revision of Departmental Documents.

(Officer/Executive)

Respective Departments: Review, Training and Effective Implementation of Departmental Documents.

4.0 ACCOUNTABILITY:

Respective Departments Heads: To ensure Training and effective Implementation of Departmental Documents.

Head QA: To ensure Compliance with the SOP.

5.0 DEFINITIONS:

5.1 Document:

The definition of Good Documentation Practice (GDP) describes standards by which documentation is created and maintained in the pharmaceutical industry. Although the U.S. Food and Drug Administration (FDA) sets some GDP standards, others fall under the current Good Manufacturing Practice (cGMP). All pharmaceutical, bioscience and healthcare companies, as well as their vendor partners, must observe GDP or face warnings or penalties levied by the FDA.

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6.0 PROCEDURE:

Note: Do not use Gel / Fountain Pen for Signing and Filling the documents.

6.1 DOCUMENTS TRAINING, CONTROL, ISSUANCE AND RETRIEVAL:

6.1.1 All Master documents once finalized, shall be printed on A4 size plain white colored Paper (75 GSM) using **"Times New Roman"** Font size 12 with Black Ink.

6.1.2 Printing of Master Documents shall be done on one side of the paper only and shall be signed off with Blue Ink ball point pen by all stakeholders.

6.1.3 SMF, VMP and other Manuals shall be printed on A4 size White Colour Glossy Paper of 100 GSM (Except Cover Page, Cover Page shall be printed on A4 Size White Photo Paper of 180 GSM) with Colour Printing. Printing shall be done on one side of the paper only.

6.1.4 Training shall be imparted by SME/Manager/Head of the User Department to the concerned department and Cross-functional departments with respect to Master document.

6.1.5 Post training, Documents shall be made effective within 10 working days and effective date shall be written in respective column of Header with Blue Ink Ball Point Pen.

6.1.6 Master copy shall be stamped as "MASTER COPY" on all pages with Blue colour ink as per Annexure-I, Titled "Name and Specimen of Stamps for Plant Quality Assurance" and shall sign and date with Blue Ink Ball Point Pen

6.1.7 After photocopying of master copy, all pages shall be stamped as "CONTROLLED COPY" with green colour ink and sign and date with Black Ink Ball Point Pen as per Annexure-I.

6.1.8 All controlled copy of Documents / Spiral binded Log books / Registers etc. of all the departments shall be issued by QA after receiving the Request Form for Issuance of Documents as per format shown in **Annexure-II**, Titled **"Request Form for Issuance of Documents"**.

6.1.9 QA shall affix issuance slip as per format shown in Annexure-III, Titled "Bound Book / Register Issuance Slip" on the back side of front cover page of Bound Book (Registers, Ledgers, Duplicate / Triplicate Book / Spiral binded Log Books and Pre Printed forms) and Controlled Copy stamp shall be on the right corner of the slip.

6.1.10 In case controlled copy of Documents are to be carried out for external / internal purpose, shall be authorized by Head QA as per Annexure-II, Titled "Request Form for Issuance of Documents".

6.1.11 Additional Page (for recording additional entries) shall be issued by QA after filling the Request Cum Issuance Form for Additional Pages as per format shown in Annexure-IV, Titled "Request cum Issuance Form for Additional Pages".

6.1.12 QA shall maintain the Issuance, Retrieval and Destruction Record of loose Formats/Annexures as per format shown in Annexure-V, Titled "Formats Issuance, Retrieval & Destruction Log".

6.1.13 QA shall maintain the Issuance, and Retrieval of bound books/Registers or spiral binded log books as per format shown in Annexure-VIII, Titled "Log Books/Register Issuance & Retrieval Log".

6.1.14 All retrieved copies of unexecuted documents (Annexures) issued to Plant shall be collected by QA Department on monthly basis and destroyed with the help of Paper Shredder or manually for disposal.

Note: Loose formats/Annexures issued on monthly basis shall be utilized within the same month, remaining copy shall be retrieved to QA and new formats/Annexures to be issued for the next month.

6.1.15 Log books of the plant shall be retrieved immediately after completion and at the end of calendar year as per applicability and details of retrieval shall be recorded in Annexure-VIII.

6.1.16 All controlled Retrieved Documents shall be archived in QA Department with lock and key arrangements.

6.1.17 All Documents and Records shall be stored in a manner to protect them from damage, loss and deterioration.

6.1.18 Documents & Records shall be easily retrievable.

6.1.19 All personnel shall use Black Ink Ball Point Pen for recording the data.

6.1.20 IPQA personnel shall use Green Ink Ball Point Pen for data entry in the documents (BMR & BPR and Verification Part of Log Books/Formats/Registers etc.)

Note: Change History Log shall be part of all documents.

6.2 SPECIMENS OF STAMP:

6.2.1 Specimen of Stamps having Department name as **"Quality Assurance"** are for the Documents controlled by Quality Assurance as shown in **Annexure-I**.

6.2.2 All Stamps shall be kept in lock & key in QA.

6.2.3 For Specimen of Stamps Location refer as per format shown in **Annexure-VII**, Titled **"Stamps Location (Specimen Copy)"**.

6.2.4 **MASTER COPY STAMP:**

6.2.4.1 Master Copy of documents shall be stamped as '**MASTER COPY'** in Blue color ink below square space or right upper corner of the page provided in Header on all the pages and shall be signed by **Blue Ink Ball Point Pen**.

6.2.5 **CONTROLLED COPY STAMP:**

6.2.5.1 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**. For issuance of documents other than SOP **"CONTROLLED COPY"** stamp without Copy No. shall be used in Green ink in the right upper corner of the page.

6.2.6 **ADDITIONAL PAGE STAMP:**

6.2.6.1 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.

6.2.7 **UNCONTROLLED COPY STAMP:**

6.2.7.1 Copy of Document that is meant to be submitted/provided to the External Agency (i.e. Regulatory, Customers / Partners etc.) shall be made by Photocopy of Master Copy or executed documents (Filled BMR/BPR, Log Books, Reports and any other executed formats etc.) by QA and shall be stamped as **'UNCONTROLLED**

COPY' in Red Ink on left corner of the page below footer and shall be signed by **Black Ink Ball Point Pen**.

Note: Uncontrolled copy of Documents shall not be issued within the entire Organization for internal use.

6.2.8 **OBSOLETE COPY STAMP:**

6.2.8.1 Obsolete 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.**

6.2.9 **DISCONTINUED COPY STAMP:**

6.2.9.1 Master Copy of Documents which is discontinued 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**.

6.2.10 **REVIEWED STAMP:**

6.2.10.1 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.**

6.2.11 **REFERENCE COPY STAMP:**

6.2.11.1 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**.

6.2.12 **DISPLAY COPY STAMP:**

6.2.12.1 Documents which are issued for display purpose shall be stamped as **"DISPLAY COPY"** in Violet ink on bottom right corner.

6.2.13 **APPROVED BY STAMP:**

6.2.13.1 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.

6.2.14 **REVISION OF DOCUMENTS:**

6.2.15 Any change required in the document shall be done at any time during the period after due authorization of Change Control.

6.2.16 Periodic review of documents shall be done through change control Procedure.

6.2.17 For discontinuation of any document mention "Discontinued" in the remarks column of Document Master List.

6.2.18 QA shall inform to Department Head prior 30 days for revision of Documents which is to be reviewed.

Note: The soft copy of Documents shall be provided to respective departments one month in advance from the next due date of revision.

6.3 LIFE CYCLE & DESTRUCTION OF DOCUMENTS (MASTER AND EXECUTED):

6.3.1 All the Obsolete/Discontinued hard copy of Master Document (i.e. MFR, BMR & BPR etc.) shall be scanned and retained in soft copy with back up facility for life cycle from the date of Obsolete/Discontinued document.

6.3.2 Hard copy of Obsolete/Discontinued Master Document shall be stored for Five years and destruction shall be done as per format shown in **Annexure-VII**, Titled **"Master/Executed Document Destruction Record"**.

6.3.3 After five year, Obsolete/Discontinued/Executed document shall be destroyed through paper shredder/manually.

6.3.4 In case if any legal Complain/Issue is noticed then necessary documents / data covering that complaint/issue shall be retained till the resolution of such issues.

6.3.5 Product Quality Review, Process Validation Protocols/Reports, Stability Data & Documents, Qualification & Validation Documents for critical Utilities/System/Equipments, Clinical Trials, Bioavailability & Bioequivalence, Toxicological studies shall be retained till the life of the organization.

6.3.6 (BMR, BPR and Analytical data) and other product related documents and logbooks shall be preserved up to Product Expiry plus one Year and thereafter QA shall destroy by paper shredding machine/manually.

6.3.7 QA shall maintain the destruction record of Executed (BMR, BPR, and Analytical data).

6.3.8 All Certificates, Equipment/Machines Manuals (Original Copy) shall be retained till the life of the organization by Quality Assurance Department with lock and key arrangements.

6.3.9 Calibration records, Equipment Log & Machine Log shall be preserved up to Five Years.

6.4 DATA CONTROL:

6.4.1 All the data maintained in software shall be protected by Password accessible to Head QA / respective Head of the Plant specific Department/and their designee.

6.4.2 Archiving of data in External Hard Disc/ Soft Backup/ Hard Backup shall be done by IT Department and shall be kept under lock and key.

6.4.3 The distribution of data to other than user shall be done only after approval of Head QA.

6.5 SITE MASTER FILE (SMF) AND VALIDATION MASTER PLAN (VMP):

6.5.1 The first page annexure of validation master plan Logo height 1.41” and width 2.89”.

6.5.2 The revision period for SMF & VMP shall be of 02 years, if there is any change in the document, amended with date & page no. shall be placed with the document.

Document No. For site master file should be……

Document No. for validation master plan should be……

6.5.3 Annexure of the SMF & VMP shall be revised as and when required.

6.6 NUMBERING SYSTEM FOR MANUALS:

6.6.1 Document No. for Quality Manual shall be ……

6.6.2 Further number for Manuals shall be given in the same sequence with increase in serial number.

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7.0 ABBREVIATIONS:

QA	Quality Assurance
IPQA	In-process Quality Assurance
Ltd.	Limited
MFR	Master Formula Record
No.	Number
PDF	Portable Document Format
QC	Quality Control
S.No.	Serial Number
SMF	Site Master File
SOP	Standard Operating Procedure
STP	Standard Test Procedure
STS	Standard Test Specification
VMP	Validation Master Plan

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Name and Specimen of Stamps for Plant Quality Assurance	
Annexure-II	Request Form for Issuance of Documents	
Annexure-III	Bound Book/Register Issuance Slip	
Annexure-IV	Request cum Issuance Form for Additional Pages	
Annexure-V	Formats Issuance, Retrieval & Destruction Log	
Annexure- VI	Stamps Location (Specimen Copy)	
Annexure-VII	Master/Executed Document Destruction Record	
Annexure-VIII	Log Books/Register Issuance & Retrieval Log	

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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

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.
- FDA Q7A Good manufacturing practice Guidance for active Pharmaceutical Ingredients, Section VI, and Documentation and Data Control.
- ICH Good manufacturing practice guide for API Q7, Section 6 Documentation and Records.
- ISO 9001-2008, Clause 4.2: Documentation requirements.
- Guide to GMP for medicinal products Part-1, chapter 4 Documentation PIC/S PE 009-8 (Part I).
- EudraLex, The Rules Governing Medicinal Products in the European Union, Volume 4, Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use.

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		

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ANNEXURE–I

NAME AND SPECIMEN OF STAMPS FOR PLANT QUALITY ASSURANCE

NAME OF THE STAMP	SPECIMEN OF STAMP	NAME OF THE STAMP	SPECIMEN OF STAMP
MASTER COPY		**UNCONTROLLED COPY**	
CONTROLLED COPY		**OBSOLETE COPY**	
CONTROLLED COPY No. (Only for SOP)		**DISCONTINUED COPY**	
DISPLAY COPY		**REFERENCE COPY**	
REVIEWED		**ADDITIONAL PAGE**	
APPROVED BY			

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ANNEXURE–II

REQUEST FORM FOR ISSUANCE OF DOCUMENTS

Date:

To,
The Manager QA

From:

S.No.	Document Title	Page/Document No.	No. of Copies Required	External/ Internal Purpose	Reason for Issuance

Prepared By
Initiating Department
(Sign & Date)

Checked By
Head of the Department
(Sign & Date)

Approved By
Head QA
(Sign & Date)

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ANNEXURE–III

BOUND BOOK/REGISTER ISSUANCE SLIP			
Title of Document:			
Format No.:		**Effective Date:**	
Department Name:			
No. of Pages:		**From** _____ **To** _____	
Issued By **Officer/Executive QA** **(Sign & Date)**		**Approved By** **Manager QA** **(Sign & Date)**	

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ANNEXURE–IV

REQUEST CUM ISSUANCE FORM FOR ADDITIONAL PAGES

Date:

To,
The Manager QA
From:

S.No.	Document/ Format Title	Document/ Batch/Format No.	Page No.	No. of Copies Required	Reason for Issuance

Prepared By
Officer/Executive
(Sign & Date)

Checked By
Head of Department
(Sign & Date)

Approved By
Manager QA
(Sign & Date)

Additional Pages Issued By QA
Officer/Executive
(Sign & Date)

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ANNEXURE – V
FORMATS ISSUANCE, RETRIEVAL & DESTRUCTION LOG

Department: **Month:** **Year:**

Issuance						Retrieval			Destruction		
Date	Format Title	Format Number	No. of Copy Issued	Issued By Sign & Date	Received By Sign & Date	No. of Copies Retrieved	Retrieved By Sign & Date	No. of Unfilled Copies Retrieved	Unfilled Copy Destroyed By Sign & Date	Checked By Sign & Date	Remarks

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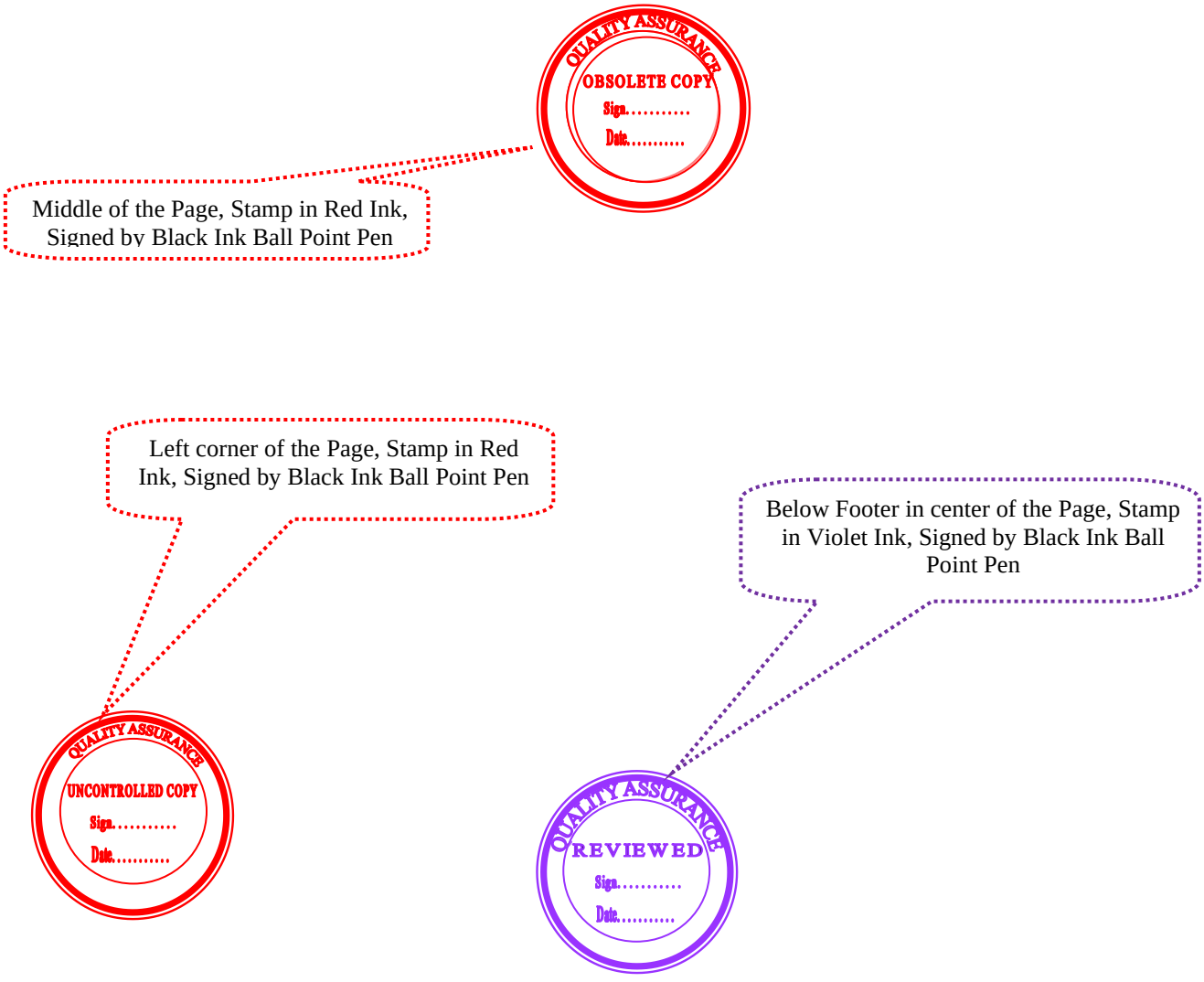
ANNEXURE – VI
STAMPS LOCATION (SPECIMEN COPY)



DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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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 Pen

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 Pen

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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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

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ANNEXURE–VII

MASTER/EXECUTED DOCUMENT DESTRUCTION RECORD

S.No.	Document Title	Document No.	Document Type	Date of Destruction	Destruction Done By (Sign & Date)	Destruction Checked By (Sign & Date)	Reason for Destruction

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ANNEXURE–VIII

LOG BOOKS/REGISTER ISSUANCE & RETRIEVAL LOG

Department: **Month:** **Year:**

Issuance							Retrieval			
Date	Title of Document	Format Number	No. of Copy Issued	Log Book Number	Issued By Sign & Date	Received By Sign & Date	No. of Copies Retrieved	Retrieved By Sign & Date	Received by QA	Remarks