DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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

1.0 OBJECTIVE:

To lay down a Procedure for Good Documentation Practices.

2.0 SCOPE:

This SOP shall be applicable to Good Documentation Practices (GDP) for all Departments at ……...

3.0 RESPONSIBILITY:

3.1 **QA (Officer/Executive):**

Preparation, Distribution, Revision, Retrieval and Destruction of this SOP.

3.2 **QA Manager:**

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

4.0 ACCOUNTABILITY:

4.1 **Head QA :**

4.1.1 Approval, ensure Training and effective implementation of this SOPs at plant.

4.1.2 To ensure retrieval of this SOP.

Note:

- ***Each Employee shall be responsible to ensure the adequacy and accuracy of his or her Documentation.***
- ***All Head of the Respective Departments or Area Supervisor / In-Charge shall be responsible to ensure Errors correction & date and time pattern as per this SOP.***

This SOP is not applicable to any Correction in Master Documents and Text Matter of Controlled Documents

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5.0 DEFINITIONS:

5.1 **Good Documentation Practices:** Good documentation practices (GDP) are those measures that collectively and individually ensure documentation, whether paper or electronic, is attributable, legible, traceable, permanent, contemporaneously recorded, original and accurate.

Documentation is a Process, which comprises of the following:

- Recording of data
- Review of Documents
- Approval of documents
- Issuance and Archival of documents
- Retrieval of documents
- Presentation of Documents

5.2 **Errors:** Error can be defined as a mistake that can happen while Data Entering, Recording, Writing and Signing in any Documents. The Error does not mean Printing Error of Text Matter in Master and Controlled Documents.

5.3 **Signature:** The script name or unique identification mark executed to authenticate an action, identify the responsible person and/or use evidence of approval.

5.4 **Specimen Signatures:** Signature of an employee to proof authenticity of a person who is signing the documents. Specimen Signatures shall provide documentary evidence for signing the particular documents and performing particular jobs.

6.0 PROCEDURE:

6.1 Good Documentation Practices (GDP) involves Correction during Data Entering, Recording, Writing, Signing in Formats, Logs, Protocols and Registers used by various Departments including Specimen signature log and Time, Date Formatting procedure etc.

6.2 Document shall be concise, legible, accurate and traceable with all associated metadata required to reconstruct the cGMP activity. Legible hand writing entries shall be made using indelible ink. Overwriting shall not be allowed. Ditto (–,,–) marks and continuation lines shall not be used.

6.3 Overwriting in the executed documents and data entries is strictly prohibited.

6.4 In Case any error occurs, concerned person shall not overwrite nor use any Gel Pen, Pencil, Correction Fluid, Labels, Erasers, or Corrective Tape to correct the Error.

6.5 Error shall be corrected by striking through Single Line over the Word/Sentence/Data so that original Word / Sentence / Data are legible.

6.6 Concerned person shall write the corrected Word/Sentence near the strike off Error with Sign and Date.

6.7 In all the documents of the plant where signature are required concern person shall sign. as per the Specimen. For details refer SOP (Specimen Signatures).

6.8 Data shall be recorded directly and promptly while performing the activities indelibly in spaces provided for such entries. No data shall be written on scrap paper, rough paper or personal notebooks.

6.9 Backdating and postdating are prohibited.

6.10 All the printouts of the raw data shall be signed and dated.

6.11 All pages shall be paginated. Attachments (supporting documents) shall be paginated with reference to the parent document.

6.12 In case of executed documents, i.e. wrong entry, writing error, spell error, Calculation error, Transcription error & signing error etc. that is case specific, justification for the correction with strike out appropriately above, beside or bottom of the page shall be done with sign & date of concerned person and same shall be verified with impact assessment by HOD with sign & date .

6.13 If the original value or data has been changed after correction, the person shall also mention the reason of change adequately.

6.14 In case of Typographical error in record and report prepared by computer system, write justification for the correction with asterisk (*) mark and sign & date at the bottom of the page or beside wherever sufficient space available by prefixing the (*) to the reason of the correction (e.g. if the cause of the error is Typographical Error, write **'Typographical Error'** (Typo. Err.), etc.).

6.15 In case there is more than one correction for which reasoning is required and no space is available then for each correction an asterisk (*) is marked along with Sr. No. of correction e.g. *1,*2,*3 and such reasons shall be explained at the bottom of the page or at available space by prefixing with *1,*2,*3 as the case may be with sign & date of initiator and shall be counter signed by Head of Department with Sign and Date.

6.16 In case of missing entry observed when next entries are done, Put an asterisk (*) and make entry on the next available line or space and record the reason with Sign and Date. Further, in case of multiple corrections (i.e. more than one on single page) shall be counter signed by Head of Department with Sign and Date.

6.17 In case any document has more than one copy, then correction shall be done simultaneously in all copies; such correction shall be done by concerned personnel and counter signed by QA.

6.18 In case correction required in date or time of original entry and any backup data (i.e. Printouts, related entry etc.) is available then correct the same with current sign and date by concerned person and give the reference of backup data available.

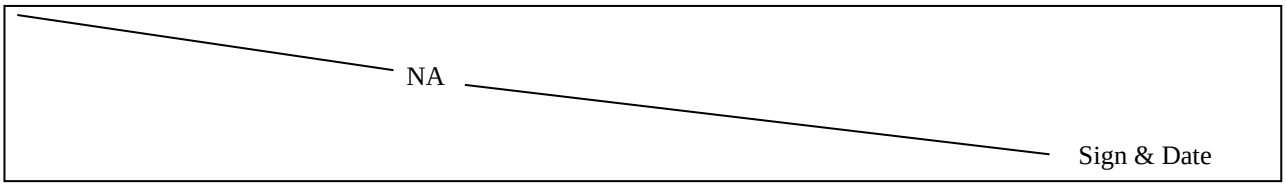
6.19 In case the ink of Printout get faded over time (e.g., thermal paper), a photocopy shall be used with verification of its accuracy; the copy shall be signed and dated.

6.20 In case of spillage of any material on page, the same page(s) photocopy shall be retained along with original page(s).

6.21 Blank or unused space in the GMP records shall be filled diagonally (from left top corner to right bottom corner) with NA i.e. “Not Applicable” in between as given below:

6.22 In case blank space is left in the record because an entry is not applicable, mention “NA” with sign & date.

Specimen Page



Details of causes	Action Taken

	NA Sign &Date

6.23 In case any error is identified in the executed document of a person who is on long leave or resigned such correction shall be done by concerned department head by giving justification and counter signed by QA.

6.24 **DATE & TIME FORMATTING:**

6.24.1 **DATE FORMATTING:**

6.22.1.1 Date entry shall be done in all the Documents as **DD/MM/YYYY** Format.

Where,

"DD" **:** Represents the Date

"/" **:** Represents Separator

"MM" **:** Represents the Month

"/" **:** Represents Separator

"YYYY" **:** Represents the Year

For Example: 25/01/2020, **25** shall represent Date, **01** shall represent the Month and **2020** shall represent the current Calendar Year.

6.22.1.2 Always use two digits for Date & Month and four digits for Year.

6.25 **TIME FORMATTING:**

6.25.1 Entry time shall be done in all documents as Twenty Four Hours Clock time.

6.25.2 Time shall be recorded in HH:MM format.

For Example: 1:40 PM shall be written as **13:40**, **12:00** Midnight shall be written as **00:00** and **12:00** Noon shall be written as **12:00**.

6.25.3 Place "0" before the digit, if the digit is less than 10 for recording the time.

For Example: Time **9:40 AM shall be written as 09:40.**

NOTE: Date & Time format on documents provided by outside agency/company may be different from this SOP which shall be acceptable.

7.0 ABBREVIATIONS:

AM	Anti Meridiem
CFR	Code of Federal Regulations
Cgmp	Current Good Manufacturing Practices
e.g.	Example
Err.	Error
Etc.	et cetera
GDP	Good Documentation Practices
HR	Human Resource
Ltd.	Limited
No.	Number
PIC/s	Pharmaceutical Inspection Co-operation Scheme
SOP	Standard Operating Procedure
QA	Quality Assurance

8.0 ANNEXURES:

Not Applicable

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 Resources Department.

- Controlled Copy No. 05 Engineering Department.
- Controlled Copy No. 06 Warehouse Department.
- Controlled Copy No. 07 Information and Technology Department.

10.0 REFERENCES:

- 21 CFR Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies.
- Guidance for Industry Part 11, Electronic Records; Electronic Signatures.
- Volume 4 Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Chapter 4: Documentation.
- Guidance on Good Data and Record Management Practices (September 2015)
- PIC/s Guide to Good Manufacturing Practice for Medicinal Products Part IUSP ⟨1029⟩ Good Documentation Guidelines.

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		