PHARMA DEVILS

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 PURPOSE:

1.1 To lay down a procedure for good documentation practices for the entry of document records and correction of documentation errors.

2.0 SCOPE:

2.1 The procedure shall be applicable for the entry of document records and correction of any documentation errors.

3.0 RESPONSIBILITY:

3.1 All the employees at the Site shall be responsible to implement the procedure.

4.0 REFERENCE:

4.1 Nil

5.0 DEFINITION:

5.1 Nil

6.0 PROCEDURE:

6.1 The information/data shall be recorded using indelible ink and in a manner easy to read.

6.2 Blue ink shall be used by all personnel for data recording.

6.3 All the entries should be made concurrent with respective activity.

6.4 The data entry shall be recorded directly on the respective document and shall not be recorded on rough books / rough papers/legal pads.

6.5 No pencils, erasers or correction fluid shall be used for any documentation purpose.

6.6 The practice of makeovers, use of ditto marks shall be prohibited.

6.7 The entry shall be recorded with signature and date.

6.8 The time entry shall be recorded based on 24 hour time basis. For example, the time entry of '0000' denotes '12.00 night', '1200' denotes 12.00 noon and '1300' denotes 1.00 p.m.

6.9 If an entry is inadvertently missed, the information shall be documented by procedure defined below-

6.9.1 Document the missing information

6.9.2 Sign and date using the current date.

6.9.3 Make a notation stating that the entry is for work performed on a specific previous date.

6.10 If any additional information is to be recorded in the document such as additional sampling performed for the validation batch, then following procedure shall be implemented –

6.10.1 Place a superscript of a number in a circle (e.g.^{①}, ^{②}) where the text/note is to be recorded.

6.10.2 Write the number in the circle at the bottom of the page, as a footnote and enter the additional information in the footnote. If the footnote space is not enough, create a separate sheet, put the superscript number on the separate sheet and add the information required.

6.10.3 Record initial with date.

6.11 If an entire paragraph / page is not pertaining to specific activity in a sequential order record e.g. log book , Packaging instructions or format, follow the procedure mentioned below-

6.11.1 Cross it out with a line, mark N/A.

6.11.2 Record initials along with date.

6.11.3 In case of correction of an erroneous entry, following procedure shall be followed –

6.11.3.1 Cross it out with a single line.

6.11.3.2 Clearly write the correct entry near the cross out.

6.11.3.3 Record initials along with date on which correction was made.

6.11.3.4 Follow step 6.10, if there is limited space.

6.12 **Corrections of typographical errors /recorded data and recording of missing data/entries:**

6.12.1 The initiator /observer shall raise "Document Ratification Request" attachment 01 (A01), for the typographical / errors in the printed text of document, errors in the recorded data/entries or for the missing entries along with reason/justification, for the proposed ratification.

6.12.2 The initiator /observer shall take the approval from QA.

6.12.3 QA shall decide the impact of the change on the previously executed documents as well as on the other documents, before authorization of document ratification form and shall enter the same in the request.

6.12.4 The 'Document Ratification Request' shall be filed along with respective document.

6.12.5 **Corrections in the printed text of the issued documents** :

6.12.5.1 The correction shall be done by the concerned person.

6.12.5.2 Cross out the word/figure/sentence with single line.

6.12.5.3 Write correct word/figure/sentence.

6.12.5.4 Write the reason for correction.

6.12.5.5 Executive Director/designee and QA shall record initials along with date.

6.12.6 **Corrections in the printed text of the 'Master Copy' and 'Controlled Copy'(if applicable) :**

6.12.6.1 corrections made on the issued documents shall then be forwarded to QA though the concerned department head for the changes to be effected on the master documents i.e. Master Copy and QA controlled copy (if applicable) the QA documentation officer after effecting the changes on the master documents shall stamp the front page of the document as,

RATIFIED ON	
(SIGN/DATE)	

6.12.6.2 QA shall record the date of ratification along with his signature.

6.12.6.3 Destroy the 'Controlled Copy' of document by shredding.

6.12.6.4 Prepare a new 'Controlled Copy' of document by photocopying the ratified document with 'Controlled Copy' stamp, on the top left corner of document.

6.12.6.5 The corrected original / master document shall be reviewed and corrected for the observed errors and shall be replaced within a period of not more than 6 months, after manual rectification of errors.

6.12.7 **Corrections in the recorded entries/data & recording of the missing entries/data in the approved/completed documents**:

6.12.7.1 The correction shall be done by the Head–user department or by a person of at least managerial cadre

6.12.7.2 Cross out the word/figure/sentence with single line.

6.12.7.3 Write correct word/figure/sentence.

6.12.7.4 Write the reason for correction & record the initials along with date.

6.12.7.5 The particular page of the document shall be stamped as.-

RATIFIED ON	
(SIGN/DATE)	

6.12.7.6 QA shall record the date of ratification along with his signature.

7.0 ATTACHMENT:

7.1 Attachment 01: Document Ratification request

8.0 VERSION HISTORY:

Version	Description of Change	Effective Date

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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ATTACHMENT-01

DOCUMENT RATIFICATION REQUEST

Title : _____

Document No.: _____

Proposed Ratification : _____

Reason for Ratification : _____

Effect on other documents (If any) : _____

Initiated By	Approved By