DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Procedure for Rectification and Correction of documents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 Objective:

To lay down a procedure for Rectification and correction of documents.

2.0 Scope:

This SOP is applicable for all documents generated in the ……..

3.0 Responsibility:

Officer, Executive – All Departments

It is responsibility of all department personnel whoever involved in documentation/data entering activity.

4.0 Accountability:

Head– Quality Assurance

5.0 Procedure:

5.1 Rectification during review of Documents:

5.1.1 During review of documents (SOP'S, BMR/BPR, PVP, STP/Specifications, Equipment qualification protocols, Formats or any other), if any corrections observed, concerned person of the department should raise Document Rectification Form (Annexure –I) with the details of correction and shall forward it to Head of Department.

5.1.2 Head of concerned department shall verify and justify the reasons for the correction and shall forward it to QA for approval.

5.1.3 QA shall allot the number to the document as follows.

5.1.4 Document Rectification Form/701

Where-

Document Rectification Form – Document Rectification Form

(/) - Slash

2 - Year of 2021

01 - Serial no.

5.1.5 In-charge QA shall verify the document and shall propose the corrective actions for Rectification and should forward it to Head – QA for final approval.

5.1.6 Head – QA shall verify the Rectification document and shall give approval/rejection.

5.1.7 If Document Rectification Form is approved, corrections shall be made in original documents by concerned department and shall be verified by Head –QA or his designee.

5.1.8 Document Rectification Form shall be filed along with original document, where Rectification has been made.

5.1.9 A register will be maintained to keep record of all Rectifications.

5.1.10 The Rectification notice will be sent to Head regulatory affairs, incase the document is submitted for filing/

registration.

5.2 Correction during data entering:

5.2.1 Strike the work/data to be changed.

5.2.2 Strike with horizontal line over word/data in such a way that original data should be legible.

5.2.3 Enter the word/data to be added on the top of the word/data to be corrected.

5.2.4 Data corrected shall be duly dated and signed by the concerned person at the right end of the corrected line.

5.2.5 Not more than three cut shall be allowed in a page.

5.2.6 If correction made is significant with respect to the subject of the record, the concerned person who makes correction shall write a reason for corrections near the corrected word / data or bottom of the respective page with Star (*) mark.

Annexure:

Annexure - I: Document Rectification form

Annexure - II: Document Rectification register

Annexure- III: Intimation of Document Rectification

Reference:

NA

Glossary:

BMR – Batch manufacturing record

BPR – Batch Packing record

PVP - Process validation Protocol

STP – Standard test Procedure

DRF- Document Rectification form

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ANNEXURE I

DOCUMENT RECTIFICATION FORM

Initiated By:		**Department:**		**Date:**
Document Rectification No.: DRF/				
Correction Related To	☐	BMR/ BPR	☐ Equipment Qualification	
	☐	Process Validation Protocol	☐ Any other	
	☐	STP/ Specification		
	☐	Format (S)		
Document Details :				
Error Observed:				
Corrective action:				
Sign		**Date:**		
Justification and Comments (HOD):				
Sign:		**Date:**		
Corrective actions and Comments – In charge QA:				
Sign :		**Date:**		
Final Approval - QA Head:				
Sign:		**Date:**		

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ANNEXURE II

Document Rectification register

S.No.	Date	Error Observed	Corrective action	Accepted/ Rejected	Document Rectification No.	Approved by	Remarks

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ANNEXURE III

Intimation of Document Rectification

From **Initiating Department**	**To** **QA**	**Date:**
Document Rectification No.: DRF/ **Document Details:**		
Error Observed:		
Correction made:		
Head - QA:	**Date:**	