DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Non-Conformances	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for handling of Non- conformances.

2.0 SCOPE:

The SOP is applicable to the Non conformances observed in ……

3.0 RESPONSIBILITY:

Officer/ Executive – All Departments

Head of the Department – All Departments

Head – Quality Assurance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 When a Non- conformance observed, concerned person of the respective department shall raise the Non Conformance Report (Annexure–II) with the details of Non-conformance and shall send it to Head of the Department of the concerned area.

5.2 Head of the department shall give his comments and the proposed corrective action, on the NCR and shall forward signed copy to Quality Assurance Department.

5.3 QA Department shall allot number to the NCR as follows:

NCR/2101

Where

NCR – Non conformance report

/ - Slash

21 - Year of 2021

01 - Serial No.

5.4 Head –QA shall investigate the NCR in co ordination with other departments and evaluate the impact of NCR on product quality, process performance, and yield, Good

Manufacturing Practices and on analytical requirements.

5.5 Head –QA shall forward NCR to other department heads for assessment and comments on the corrective actions proposed.

5.6 Other Department heads after assessing the corrective action, shall forward the NCR form back to Quality Assurance.

5.7 Based on the proposed corrective action and assessment of the other department heads, Head – QA or his designee, shall approve the NCR and shall retain the NCR for implementation of corrective action.

5.8 After approval of Head-QA, concerned department shall take corrective actions. Concerned Department head and Head-QA shall verify the corrective action taken.

5.9 A register will be maintained to keep record of all NCR's as per Annexure-I

6.0 ABBREVIATION(S):

NA

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure – I : Non-conformance Report register

Annexure – II : Non conformance Report

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION