STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Non-Compliance	**Effective Date:**
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1.0 OBJECTIVE:

To lay down a procedure for Handling of Non-Compliance.

2.0 SCOPE:

This SOP is applicable for Handling of Non-Compliance at …….

3.0 RESPONSIBILITY:

Office/Executive QA

4.0 ACCOUNTABILITY:

Head QA

5.0 DEFINITION:

An unplanned event, unexplained discrepancy or departure from written instructions (SOP, specification, Batch records, instructions, Protocol) is defined as Non-Conformance.

6.0 PROCEDURE:

6.1 After observing any discrepancy in respective area concern QA person shall log the discrepancy in non-conformance logbook of respective area in **Annexure-II**, Titled **"Non–Compliance Log Book"**.

6.2 Concern QA person shall issue controlled copy of non-conformance report in **Annexure-I**, Titled **"Non–Compliance Report"** to concern Department Head.

6.3 A unique identification no. shall be allotted to non-conformance report as per below mentioned numbering system.

NC/DD/MM/NNN

Where,

NC	**:**	denotes Non-Conformance
/	**:**	is used as a separator
DD	**:**	Denotes department code. For department code refer Table No. 01.

MM : Indicates two digits of current month. Ex: for non-conformance observed in October month 10 shall be mentioned.

NNN : Indicates serial no. of Non-conformance, given to a particular department in three numerical digits. For ex: 001,002,003……

6.4 Following Short Forms shall be Used for Department Code:

Department	Department Code
Quality Assurance	QA
Quality Control	QC
Quality Control(Micro)	QM
Ware House (RM)	RM
Ware House (PM)	PM
Ware House (FG)	FG
Engineering	EN
Production (Three Piece Line)	TP
Production (Dry Powder Line)	DP
Production (Ampoule Line-1)	A1
Production (Ampoule Line-2)	A2
Production (Liquid Vial Line)	LV
Human Resource	HR
Purchase	PU
Planning	PL

6.5 After allocation of identification no. to non-conformance report concern QA person shall describe non-conformity in detail in observation column of **Annexure –I.**

6.6 QA person shall also categorize observation as Critical/Major/Minor based on the impact of non conformity as follows:

6.6.1 CRITICAL NON-CONFORMITY:

Non-Conformity which shows high risk & have direct & indirect impact on product safety, Identity, strength, purity & quality.

6.6.2 MAJOR NON-CONFORMITY:

Non-conformity which shows moderate risk on product safety, identity, strength, purity & quality.

6.6.3 MINOR NON-CONFORMITY:

Minor non-conformity which shows low risk or No risk to product safety, identity, strength, purity & quality.

6.7 Non-conformity report shall be handover to concern department head & same shall be acknowledged by receiver in Non-conformity logbook in **Annexure-II**.

6.8 Concern department head /his& her deputy shall carry out investigation against non-conformity to identify root cause.

6.9 Against root cause suitable CAPA shall be initiated to avoid re-occurrence of Non-conformity.

6.10 After defined CAPA implementation & verification non-conformance report shall be closed, with in below mentioned time frames:

- Critical Non-Conformance: **NMT 07 Days**
- Major Non-Conformance : **NMT 14 Days**
- Minor Non-Conformance : **NMT 28 Days**

Note: deviation from the defined timelines is allowed only in cases of justified reasons.

6.11 If Non-conformance not closed within defined time period concern department head shall give delay justification to QA in the same report format & same shall be approved by QA Head.

6.12 Concern department shall handover the non-conformity report after CAPA verification to QA.

6.13 QA shall verify the impact of CAPA implementation & after verification non-conformance report shall be closed.

6.14 Trend analysis of Non-conformance shall be prepared & analyzed as per **Annexure-III**, Titled **"Trending of Non-Conformance"** on monthly basis.

6.15 Record the Non-Compliance details in **Annexure-II**.

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7.0 ABBREVIATIONS:

SOP : Standard Operating Procedure

Pvt. : Private

Ltd. : Limited

QA : Quality Assurance

CAPA : Corrective and preventive action

No : Number

8.0 ANNEXURES

Annexure No.	Title of Annexure	Format No.
Annexure-I	Non–Compliance Report	
Annexure-II	Non–Compliance Log Book	
Annexure-III	Trending of Non-Conformance	

ENCLOSURES: SOP Training Record

9.0 DISTRIBUTION:

- Controlled Copy No.1 Head Quality Assurance
- Master Copy Quality Assurance

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).

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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
NON-COMPLIANCE REPORT

Date			
Non Compliance No.			
Department		**Section**	

Observation : **Signature & Date**
Categorization of Non-Compliance: Critical/Major/Minor
Received By: **(Sign & Date)**
Root Cause of the NCR: **Signature & Date**
Corrective Action : **Signature & Date**
Preventive Action : **Signature & Date**
Delay Justification : (If applicable)

Department Head	**QA-Head**
Name :	**Name** :
Signature & Date	**Signature & Date**
Closing Comments:	

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(Concerned Department Head)
(Sign & Date)

Verification of CAPA:

(Quality Assurance Department)
(Sign & Date)

Approved By:

Head –QA
(Sign & Date)

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ANNEXURE-II
NON-COMPLIANCE LOG

S.No.	Issue Date	NC No.	Department Name	Category of NC	Observation	Received By Sign & Date	Compiled On	Remarks

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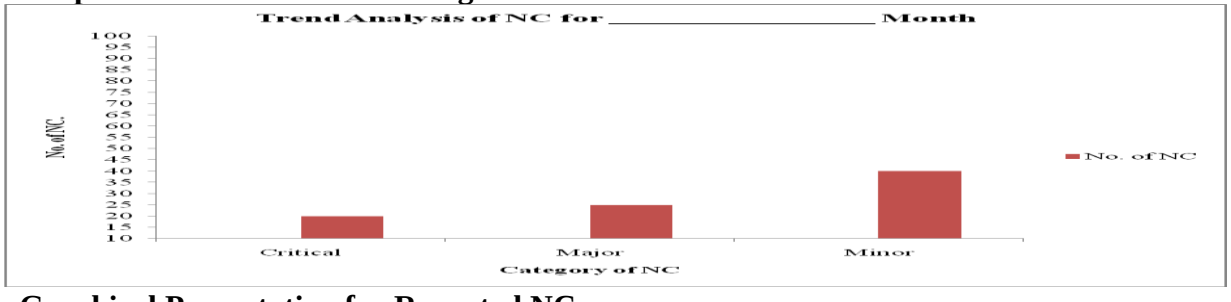
ANNEXURE-III
TRENDING OF NON-CONFORMANCE

Trend analysis of Non-Conformity for _____ month _____ year.

S. No.	Category of Non-Conformance	Total No.
1.	Critical	
2.	Major	
3.	Minor	

Graphical Presentation for Categorization of NC:



Graphical Presentation for Repeated NC: