PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of Laboratory Deviation	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To establish a procedure for deviation in Quality Procedures.

2.0 SCOPE:

This procedure is applicable to Quality Procedures and related formats.

3.0 RESPONSIBILITY - Execution - Executive QC.
Checking - Assistant Manager QC .

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 Any deviation from established specifications or requirements stated in Quality System documents, which can affect the safety, identity, strength, purity or quality of the drug product are identified.

5.2 For deviation in documents other than quality Manual, Quality Procedure Manual and related formats, (Handling of Deviation) and (Incident Reporting System) shall be followed.

5.3 No deviation is allowed without the prior approval of Quality Manager/ Technical Manager.

6.0 SAFETY & PRECAUTIONS:

Not Applicable

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date

8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

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9.0 **REFERENCES:**

Handling of Deviation
Incident Reporting System

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

No. : Number

QC : Quality Control

ANNEXURES - Not Applicable