POLICY ON DEVIATION HANDLING

INTRODUCTION:

This document provides the policy on the manner in which ..... handles the deviations to any approved instruction or established standard is a deviation.

SCOPE:

This policy is applicable to all GxP operations at ..... and its associated units.

POLICY DETAILS:

- ✧ A written procedure for handling deviations shall be in place.
- ✧ Deviations shall be recorded, investigated in a timely manner and root cause shall be identified. The impact of the deviation shall be assessed and the deviation shall be categorized.
- ✧ Corrective and preventive actions shall be implemented to mitigate the risks arising from deviations. Deviation shall be closed as per defined timelines.
- ✧ Deviation related to product shall be reviewed before batch release.
- ✧ Periodic trend analysis of deviations shall be performed as part of continuous improvement. Deviation and supporting documents shall be retained as per set procedure.

AMENDMENT AND WAIVER:

The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION:

Any departure from an approved instruction or established standard or any incident that could affect product quality or the reliability of records is a deviation.

ABBREVIATIONS:

CFR	:	Code of Federal Regulations
GxP	:	Good X Practices where x stands for Manufacturing, Laboratory, Clinical and Distribution
ICH	:	The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
WHO	:	World Health Organization

REFERENCES :

WHO Technical Report Series
961 ICH Q7
21 CFR