POLICY ON CAPA

INTRODUCTION:

This document provides a policy which is designed to provide guidance on the manner in which ……. establishes CAPA in a timely manner, which would result in product and process improvements and its enhanced understanding.

SCOPE:

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

POLICY DETAILS:

- ✧ ….…….. shall have in place a documented system for implementing corrective actions and preventive actions.
- ✧ CAPA may result from the investigation of complaints, rejections, recalls, deviations, audits, regulatory inspections, trends from process performance and product quality monitoring, risk management, OOS, OOT, analytical incidences, validations, stability evaluation etc.
- ✧ Each CAPA shall be logged and shall bear a unique identification number.
- ✧ CAPA team shall comprise of personnel with appropriate technical/regulatory knowledge. The impact of the proposed CAPA shall be assessed.
- ✧ Implementation of CAPA within a defined close out period shall be ensured. Mechanism of CAPA effectiveness review shall be in place.

AMENDMENT AND WAIVER:

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

DEFINITION:

CAPA is a concept within GMP which focuses systematic investigation of discrepancies in an attempt to eliminate the causes of an existing / potential non conformity and prevent their recurrence.

ABBREVIATIONS:

CAPA : Corrective Action and Preventive Action GMP: Good Manufacturing Practices
GxP : Good X Practices where x stands for Manufacturing, Laboratory, Clinical and Distribution.
ICH : International Conference on Harmonization
OOS : Out of Specification
OOT : Out of Trends
WHO : World Health Organization

REFERENCES:

WHO Technical Report Series
961 ICH Q10