POLICY ON CHANGE MANAGEMENT

INTRODUCTION:
This document provides the policy for change management which assures continual state of control and provides a high degree of assurance that there are no unintended consequences of change.

SCOPE:
This policy applies to changes related to product, process, equipment, instrument, document, system and facility within …… and Associated units.

POLICY DETAILS:
- ✧ A formal procedure shall be in place for change management.
- ✧ All GxP related changes shall follow change management process. The potential impact of the proposed change shall be assessed.
- ✧ Changes shall be categorised depending on the nature and extent of change. Only approved change proposal shall be implemented.
- ✧ Implementation of change shall be identified with the appropriate effective/ implementation date. Change control shall be monitored for close out.
- ✧ Change control documents along with supportive documents shall be retained as per defined procedure. Where an electronic system is used, it shall be appropriately qualified.
- ✧ Post implementation review shall be done to confirm the change objectives were achieved.

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

DEFINITION:
GxP: The underlying international pharmaceutical requirements, such as those set forth in the US FD&C Act, US PHS Act, FDA regulations, EU Directives, Japanese regulations, or other applicable national legislation or regulations under which a company operates. These include but are not limited to:
- ➢ Good Manufacturing Practice (GMP) (Pharmaceutical, including API)
- ➢ Good Clinical Practice (GCP)
- ➢ Good Laboratory Practice (GLP)
- ➢ Good Distribution Practice (GDP)
- ➢ Good Quality Practice (GQP)
- ➢ Good Pharmacovigilance Practice
- ➢ Medical Device Regulations
- ➢ Prescription Drug Marketing Act (PDMA)

ABBREVIATIONS:

API	: Active Pharmaceutical Ingredient
EU	: European Union
FDA	: Food and Drug Administration.
GxP	: Good X Practices where x stands for manufacturing, laboratory, clinical, distribution
GMP	: Good Manufacturing Practice.
ICH	: The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.
US PHS	: United States Public Health Service.
WHO TRS	: World Health Organization Technical Report Series.

REFERENCES:
ICHQ10 : Guidance for Industry, Pharmaceutical Quality System Health Canada GMP Guidelines Orange Guide
WHO TRS 908 : Specifications for pharmaceutical preparations