

POLICY ON BACKUP & RESTORATION

INTRODUCTION:

This document provides the policy for backup and restoration of the data generated, stored, maintained, transferred by computerized systems with a high degree of assurance that will consistently ensure the availability and control information or data required for supporting the quality attributes.

SCOPE:

This policy applies to all computerized systems in and its associated units that capture, store or process data falling within the scope of GxP regulations.

POLICY DETAILS:

- ✧ All the requirements covered under the Information Security Policy of “Data Backup and Archival” Policy shall prevail.
- ✧ There shall be a procedure in place for management of backup and restoration of data. Backup of all the computerized systems shall be taken at predefined interval.
- ✧ At least two copies of the backup shall be maintained of which one copy shall be stored in secure remote location under controlled access.
- ✧ The success and failure of backup activity results shall be recorded.
- ✧ The backup and restoration procedure for each software/application shall be validated and revalidation shall be performed at a predefined interval.

AMENDMENT AND WAIVER:

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

DEFINITION: Not Applicable

ABBREVIATIONS:

CFR	:	Code of Federal Regulations
EU	:	European Union
GAMP	:	Good Automated Manufacturing Practice
GxP	:	Good X Practices where x stands for manufacturing, laboratory, clinical, distribution
ISP	:	Information Security Policy
JP	:	Japanese Pharmacopoeia
MCC	:	Medicines Control Council
MHLW	:	Ministry of Health, Labour and Welfare
PIC	:	Pharmaceutical Inspection Co-operation Scheme

REFERENCES:

GAMP-5
21 CFR part 11
MCC Guidelines chapter 5 Annex.11
EU Annex 11
PIC/S 15th Jan. 2009
JP Guidances (MHLW)
ISP #12 Data backup and archival policy