POLICY ON VALIDATION OF COMPUTERIZED SYSTEMS

INTRODUCTION:
This document provides the policy for Validation of Computerized Systems with a high degree of assurance that …… will consistently produce, control information or data which meets pre-determined specifications and quality attributes. The dependence on computerised system by business processes that have direct impact on product quality is growing. …… recognizes the contribution of computerised systems to its business processes. It also realizes the need to design and implement a computerised system validation policy in order to fulfil its commitment to product quality, patient safety and data integrity.

SCOPE:
This policy applies to all Computerized systems in …….. that capture, store or process data, and are used to make decisions concerning processes falling within the scope of GxP regulations.
All the computerized systems either procured, developed in house.

POLICY DETAILS:
- ✧ All the GxP relevant computerized systems shall comply with the local regulatory requirement.
- ✧ Validation of computerized systems shall include the validation of the hardware (including network, interfaces) and the software.
- ✧ Procedures shall be in place to ensure the integrity of a computerized system throughout its operational life cycle.
- ✧ Roles and responsibilities for managing the validation activities shall be defined and documented. There shall be an approved Validation Plan (VP) to execute the validation of the computerized system.
- ✧ The Validation Plan at the minimum shall include the roles and responsibilities, validation deliverables as applicable and the testing strategy.
- ✧ Validation shall be executed through a pre-approved protocol and conclusion of the validation status shall be made at the end of the exercise.
- ✧ All the documents related to validation shall be reviewed and approved by competent authority. Only validated and approved computerized systems shall be released for use.
- ✧ The backup of the documents shall be as per the predefined procedure.

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 Processes
GxP	:	Good X Practices where x stands for manufacturing, laboratory, clinical, distribution.
JP	:	Japanese Pharmacopoeia
MCC	:	Medicine Control Council
MHLW	:	Ministry of Health, Labour and Welfare
PIC	:	Pharmaceutical Inspection Co-operation Scheme
VP	:	Validation Plan

REFERENCES:

GAMP-5
21 CFR parts 11
MCC Guidelines chapter 5
Annex.11 EU Annex 11
PIC/S 2011
JP Guidances (MHLW)