POLICY ON CALIBRATION

INTRODUCTION:

This document provides policy for Calibration of equipment and instruments that could have an impact on the product quality, safety or efficacy of the product.

SCOPE:

This policy is applicable to all equipments, instruments, measuring systems used in …….. and its Associated Units.

POLICY DETAILS:

- ✧ Control, weighing, measuring, monitoring and test equipments which are critical for assuring the quality of product shall be calibrated according to written procedures and an established schedule.
- ✧ Equipment and instruments that may have an impact on product quality must be designed to ensure adequate and suitable execution of calibration activity.
- ✧ Equipment calibrations shall be performed using standards traceable to certified standards. Calibration must be assessed against documented and authorized tolerance limits.
- ✧ Records of these calibrations shall be archived.
- ✧ The current calibration status of equipment shall be known and verifiable. Only Instruments, equipment that meet calibration criteria shall be used.
- ✧ Deviation from approved standards of calibration on critical instruments shall be investigated to determine if these could have an impact on the quality of the product manufactured using this equipment since last successful calibration.
- ✧ Computer programme used to manage and control calibration activity must be validated.
- ✧ Recalibration shall be performed in case of repair after breakdown of any instrument and or equipment Non Calibration of any instrument and or equipment shall be justified and documented.
- ✧ In case of sub contracting of calibration activity, Agreements shall be in place. Records received shall be reviewed by authorized ……. personnel for its completeness and compliance
- ✧ The person responsible for calibration control programs shall be qualified and trained.

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
ICH	:	The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
WHO	:	World Health Organization

REFERENCES:

ICH Q7 – Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.
21CFR – Code of Federal Regulations Title 21 – sec.211.160
WHO – TRS 902 (2002)