POLICY ON IN-PROCESS CONTROL

INTRODUCTION:

This document provides the policy for **In-Process Controls** to be performed during manufacturing of drug substances and drug products.

SCOPE:

This policy is applicable to manufacturing of drug substances and drug products at …….. and its associated units.

POLICY DETAILS:

- ✧ There shall be written procedure for in-process controls.
- ✧ In-process controls and their acceptance criteria shall be established based on the information gained during the development stage or historical data.
- ✧ In-process controls shall be performed by trained personnel and at pre-defined frequency.
- ✧ In-process checks shall be performed & documented during manufacturing of drug substances and drug products.
- ✧ In process data unless part of regulatory submission shall be used for impact assessment, batch release decision shall be based on finished product testing results only.
- ✧ Any non-conformance related to in-process controls shall be documented and investigated.

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: International conference on harmonization. WHO TRS: World health organization technical re
port series.

REFERENCES:

21 CFR Part 211	:	Current good manufacturing practice for finished pharmaceuticals.
ICH Q7	:	Good manufacturing practice guide for active pharmaceutical ingredients.
WHO TRS 908	:	Guidelines on WHO expert committee on specification for pharmaceutical preparation.