POLICY ON GOOD DOCUMENTATION PRACTICES & DOCUMENTATION

INTRODUCTION:

This document provides the policy for Good Documentation Practices which is essential part of the quality assurance system and is key to operating in compliance with cGMP requirements.

SCOPE:

This Policy is applicable to all types of documentation (i.e. paper-based, electronic or photographic media) carried out across …… & its associated units which is directly or indirectly impact on all aspects of the quality of medicinal products.

POLICY DETAILS:

- ✧ There shall be written procedure for preparation, issuance, recording, storage, retention & destruction of documents.
- ✧ The prepared documents shall bear a unique identification number.
- ✧ The content of document shall be clear, accurate, unambiguous and legible and there shall be appropriate controls in place to ensure the accuracy, integrity, availability and legibility of documents.
- ✧ Documents shall be approved, signed and dated by the responsible persons.
- ✧ There shall be system in place to control revision, superseding and withdrawal of all documents to prevent inadvertent use of superseded version.
- ✧ All data recordings shall be in real time.
- ✧ Any alterations made in written document, shall be signed and dated.
- ✧ No correction (grammatical, typographical) shall be made to approved documents with ink.
- ✧ Any changes in document shall be undertaken through change management or shall be supported with appropriate justification.
- ✧ If documentation is handled through electronic system, only authorized persons shall have access to enter or modify data in the system and there shall be a record of changes and deletions.
- ✧ Electronic signatures used on documents shall be authenticated and secured. There shall be system in place for backup of electronic data.
- ✧ Retention period of document shall be defined and retained as per pre-defined frequency.
- ✧ Appropriate controls shall be in place to ensure the integrity of the record throughout the retention period. Any non-conformance to good documentation practice shall be handled through deviation.
- ✧ All the employees shall be trained on good documentation practice at least once in every two years.

AMENDMENT AND WAIVER:

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

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DEFINITION: Not Applicable.

ABBREVIATIONS :

CFR	:	Code of Federal Regulations
cGMP	:	current Good Manufacturing Practices
ICH	:	International Conference on Harmonization
WHO TRS	:	World Health Organization Technical Report 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 Annexure.
Eudralex Volume 4:Good Manufacturing Practice Medicinal Products for Human and Veterinary Use : Chapter 4: Documentation