POLICY ON CLEANING & SANITISATION

INTRODUCTION:

…….. is committed to ensure that the facility and equipment are maintained in clean and hygienic condition. This document provides the policy for cleaning and sanitation of facility and equipment.

SCOPE:
Applicable to facilities and equipment used for producing active substances and drug products at …… and associated units.

POLICY DETAILS:

- ✧ Facilities and equipment used in the manufacture of intermediates, API's and finished products shall be constructed to facilitate ease of cleaning and sanitation.
- ✧ Facilities and equipment shall be cleaned and sanitized in accordance with predefined procedures. Procedure shall be in place for cleaning and sanitization of facilities and equipment as well as acceptance criteria for effectiveness.
- ✧ Specific cleaning procedures shall be in place and cleaning frequencies defined for cleaning of areas where manufacturing, processing, and packing of products such as penicillin, hormones, vaccines, cytotoxic products, live bacterial preparations, steroids, biological products are carried.
- ✧ Procedures for cleaning shall ensure removal of physical, chemical and biological contamination and shall include responsibility, methodology, frequency and cleaning agents used at the minimum.
- ✧ Validated analytical methods shall be available to ascertain the suitability of the cleaning methods developed.
- ✧ Difficult to clean parts on equipments shall be marked to ensure cleanliness and shall be assessed during validation.
- ✧ Area / Equipment shall conspicuously indicate status of cleaning / sanitation as applicable. Procedures to store cleaned equipments / accessories until use shall be defined.
- ✧ Personnel involved in cleaning and sanitation shall have adequate training.
- ✧ Disinfectants used shall be of established efficacy and rotated at regular intervals. The alternate disinfectants used should be of different chemical types and preferably with different spectrum of antimicrobial activity. Different substrates mimicking the surfaces routinely used shall be assessed during efficacy studies.
- ✧ Where applicable, hand disinfection shall be done prior to unit operations / use of equipment. Records shall be maintained of all cleaning activity carried out.

AMENDMENT AND WAIVER:

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

DEFINITION: Not applicable.

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ABBREVIATIONS:

API	:	Active Pharmaceutical Ingredient
EU	:	European Union
ICH	:	The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
MHRA	:	Medicines and Healthcare Products Regulatory Agency

REFERENCES:

ICH Q7: Good Manufacturing Practice Guidance for API's
Volume 4 EU Guideline for Good Manufacturing Practice for Medicinal Products for Human and Veterinary use. MHRA Rules and Guidelines for Pharmaceutical Manufacture and distribution