POLICY ON CONTAMINATION CONTROL

INTRODUCTION :

This document provides the policy for contamination control. ……. is committed to producing products in accordance with cGMP to ensure that products meet the requirements of safety, efficacy, purity and quality and are fit for its intended use.

SCOPE :

Applicable to manufacturing, testing, storage and distribution activities at …… and associated units.

POLICY DETAILS :

There shall be adequate facilities, systems and procedures in place to prevent product contamination during manufacturing, sampling, testing, packaging and storage.

Materials:
Materials shall be procured from suppliers who have suitable controls to prevent product contamination. All material handling operations from receipt of material to finished product distribution shall be designed to prevent risk of contamination.

Facilities:

- ✧ Facilities design shall include controls to prevent risk of contamination and cross contamination.
- ✧ Sites with multiple facilities shall be designed to prevent risk of contamination between facilities and products.
- ✧ Access to production premises shall be restricted to authorized personnel only.
- ✧ Operations relating to the manufacture, processing, sampling and packing of products such as penicillin, hormones, vaccines, cytotoxic products, live bacterial preparations, steroids and biological products shall be performed in facilities separate from those used for other drug products for human use.
- ✧ Operations relating to production of veterinary products shall be performed in separate facilities or appropriate cleaning procedures and risk assessment shall be in place.

Equipment:

- ✧ The material of construction and design of equipment shall be such that it minimizes the release of contaminants. Appropriate procedure for cleaning of equipment shall be in place.
- ✧ Cleaned equipment shall be stored in a controlled manner that shall prevent recontamination after cleaning. Appropriate expiry periods shall be assigned to cleaned equipment.

Processing:

- ✧ All processing operations shall be conducted in a manner that will prevent product contamination.
- ✧ Manufacturing operations shall be performed in segregated, self-contained processing areas to avoid the risk of mix up or cross contamination.
- ✧ Campaign size shall be decided based on the risk of contamination.
- ✧ During processing activity all equipment along with accessories and rooms shall be appropriately labeled to prevent the risk of cross contamination.
- ✧ Line clearance procedures shall be in place.

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Personnel:

- ✧ Personnel suffering from contagious diseases and open wounds shall be refrained from working in areas where product is exposed.
- ✧ Personnel shall avoid direct contact with products / materials at all point of time.
- ✧ Personnel working in production facility shall be trained and assessed on sanitation and hygiene practices. Clothing and cleaning wipes in GMP areas shall be non-shedding type.
- ✧ Protective clothing shall be worn where products or materials are handled and appropriate gowning procedures followed to minimize the risk of microbial contamination and cross contamination.
- ✧ In any case, local legal requirements for handling of critical materials / products shall be met.
- ✧ Measures to prevent cross contamination shall be periodically reviewed for their effectiveness and amended accordingly.

AMENDMENT AND WAIVER :

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

DEFINITION : Not Applicable

ABBREVIATIONS :

API	:	Active Pharmaceutical Ingredient
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
GMP	:	Good Manufacturing Practices
ICH	:	The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
MHRA	:	Medicines and Healthcare products Regulatory Agency

REFERENCES :

21 CFR Part 211: Current Good Manufacturing Practice for Finished Pharmaceuticals
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
ICH Q7: Good Manufacturing Practice Guidance for API’s