POLICY ON ENVIRONMENTAL CONTROL

INTRODUCTION:

To provide a policy for environment requirements for manufacturing, filling, testing and storage areas.

SCOPE:

Applicable to manufacturing, filling, testing and storage areas of …….. and its associated units.

POLICY DETAILS:

- ✧ Premises shall be situated in an environment which presents minimal risk of causing contamination of materials or products.
- ✧ Where starting and primary packaging materials, intermediate or bulk products are exposed to the environment, interior surfaces (walls, floors and ceilings) shall be smooth, free from cracks and open joints, and shall not shed particulate matter and shall permit easy and effective cleaning and, if necessary, disinfection.
- ✧ Separate entry for man and material shall be in place. Entry and exit procedures shall be defined. Appropriate clothing and footwear shall be worn to maintain environmental conditions as per requirement.
- ✧ Production areas shall be effectively ventilated, with air control facilities (including temperature and, where necessary, humidity and filtration) appropriate both to the products handled, to the operations undertaken within them and to the external environment.
- ✧ The classification of the area shall be commensurate with the dosage form being manufactured. Where the product is exposed the minimum classification of Grade C shall be maintained. Handling of sterile products shall be in closed environments and where exposure of the product to the environment is unavoidable, the exposure shall be under Grade A with background of grade B.
- ✧ Toxic products shall be handled in closed environments.
- ✧ Procedures shall be in place which gives directions for performing environmental control activities which includes monitoring of viable and non-viable particulate matter. The limits for viable, non-viable particulate matter and pathogens shall be as per the requirement for the product manufactured and regulatory requirements.
- ✧ Library for all identified isolates shall be maintained

  and periodically updated. All excursions shall be

  scientifically justified.
- ✧ The trend of environment monitoring data shall be evaluated periodically and appropriate actions taken.
- ✧ The acceptance criteria for determining environmental quality and the frequency of monitoring shall depend on the stage of process and the process conditions (open, closed, or contained systems).
- ✧ Procedures shall be in place for cleaning and sanitation of the area.

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
ICH	:	The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
MHRA	:	Medicines and Healthcare products Regulatory Agency

REFERENCES:

ICH Q7A: Good Manufacturing Practice Guidance for API’s
MHRA Rules and guidelines for pharmaceutical Manufacture and distribution.