POLICY ON HEALTH & HYGIENE PRACTICES

INTRODUCTION:

This document provides a policy for health and hygiene practices to be followed by all the employees of the company to prevent contamination to the products.

SCOPE:

This policy is applicable to all employees of company and its associates and personnel visiting the facilities. This policy also applies to all contract workers, maintenance and other support service personnel involved in cGMP activities.

POLICY DETAILS:

- ♦ There shall be written procedures for health and hygiene practices which shall be understood and followed through effective training programs.
- ♦ All the personnel shall undergo an appropriate medical examination prior to employment and regularly during their tenure with organization.
- Only authorized personnel shall enter the restricted facility.
- The personnel affected by infectious disease, apparent illness or open lesions shall not be allowed to handle any manufacturing activity.
- There shall be a procedure for production personnel to wash and sanitize their hands prior to entering production area.
- ♦ Bare hand contact with material and contact parts shall be prevented.
- Unhygienic practices like smoking, eating, drinking, chewing, or storage of food, drinks in production, laboratory and storage areas shall be strictly prohibited.
- ♦ PPE's shall be used by employees for appropriate operations commensurate with the risk.
- ♦ There shall be provision for containment facility in case of manufacturing of cytotoxic, Hormonal and other potent molecules.
- ♦ All visitors shall be instructed on hygiene requirements and constantly supervised whilst in the facility.

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

cGMP : Current good manufacturing practices

PPE : Personnel protective equipment

U.S. FDA : United States Food and Drug Administration

REFERENCES:

EudraLex Volume 4, Part 1, Chapter 2: Personnel

U.S. FDA: 21 CFR Part 211