POLICY ON DESTRUCTION OF DRUG PRODUCTS & DRUG SUBSTANCES

INTRODUCTION:

This document provides policy for destruction of Drug products and Drug substances.

SCOPE:

This policy is applicable to all unused products and / or returned investigation products at …… and associated units.

POLICY DETAILS:

- ✧ Destruction shall be carried out with written authorisation by the sponsor in accordance with pre-defined written procedure.
- ✧ Destruction of unused under investigation products shall be carried out only after any discrepancies have been investigated and reconciliation has been accepted by the stakeholders.
- ✧ Products meant for destruction shall be stored in segregated and secured location.
- ✧ All packaging material of the product meant for destruction shall be defaced to avoid reuse. An agreement shall be in place with the third party vendor for destruction.
- ✧ An approved transporter shall be used to transfer goods meant for destruction to third party vendor. Destruction operations shall be recorded as per written procedure and record shall be retained.
- ✧ Destruction shall be done under supervision of authorised personnel. A dated certificate or receipt for destruction shall be maintained.
- ✧ Destruction records shall allow traceability of the batch and quantity destroyed. The local regulatory requirement shall be met at all point of time.
- ✧ There shall be no land fill followed for destruction of goods.

AMENDMENT AND WAIVER:

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

DEFINITION: Not Applicable

ABBREVIATIONS:

FDA	: Food and Drug Administration
ICH	: The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

REFERENCES:

ICH Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients FDA Guidance for industry : Product recall; including removals and correction.
Eudralex Guidance , Annexe -13