

POLICY ON REWORKING (API & INTERMEDIATE)

INTRODUCTION:

This document provides the policy for reworking of API and intermediates, which do not conform the specifications and reprocessing done to meet additional requirements of customer.

SCOPE:

This Policy is applicable for all API sites.

POLICY DETAILS:

- ✧ Procedure shall be in place to ensure that reworking activities are controlled and documented.
- ✧ Reworking shall be done by processing steps that are different from the established manufacturing process.
- ✧ Each reworking batch shall have unique batch shall have unique batch number, which shall indicate that it is a reworked batch i.e. New batch number having a prefix.
- ✧ Each reworked batch shall be tested for conformance to release specification. Validation shall be performed for reworked batches.
- ✧ Stability testing shall be performed for reworked batches.
- ✧ Where applicable appropriate approvals shall be taken before releasing the batch for shipment.

AMENDMENT AND WAIVER:

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

DEFINITION:

Reworking:

An API or Intermediates does not conform to established standards or specification and which can subjected to one or more processing steps that are differ from established or approved manufacturing process to obtain acceptance quality of API or intermediates.

ABBREVIATIONS:

API : Active Pharmaceutical Ingredient
ICH : International Conference on Harmonisation

REFERENCES:

ICH Q7 Good Manufacturing Practices Guide for API's.