

# POLICY ON RECOVERY OF SOLVENTS AND MATERIALS (API)

## INTRODUCTION:

This document provides the policy for recovery of solvents and materials used during manufacturing of API's and its intermediates.

## SCOPE:

This policy is applicable for API manufacturing ..... sites.

## POLICY DETAILS:

- 🔊 There shall be validated procedures in place for recovery of solvents and materials from mother liquor or filtrates, of reactants, intermediates, or the API and its usage in manufacturing.
- 🔊 Recovered materials and solvents shall meet approved specifications.
- 🔊 Use of recovered solvents, mother liquors, and other recovered materials shall be adequately documented.
- 🔊 Use of recovered solvent shall be restricted to specified number of batches based on recommendation of R&D and available data.
- 🔊 Recovered solvent shall not be used for cleaning equipment during product changeovers. Recovered solvents shall not be used during the final steps of manufacturing.
- 🔊 Stability shall be monitored of AP'Is manufactured using recovered solvents.
- 🔊 Recovery of solvents and materials and its usage, shall take into consideration the regulatory requirements of the country where the product is manufactured as well as the country where the product is sold.

## 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 Harmonisation of Technical Requirements for  
Registration of Pharmaceuticals for Human Use  
R&D : Research and Development

## REFERENCES:

ICH Q7 Good Manufacturing Practices Guide for Active Pharmaceutical Ingredient.