

POLICY ON BLENDING OF BATCHES (API)

INTRODUCTION :

This document provides the policy for mixing of multiple batches of API within the same specification to produce a homogeneous batch.

SCOPE :

This policy is applicable to blending of API batches atAPI sites.

POLICY DETAILS :

- ✧ There shall be procedure in place for API blending operation.
- ✧ Each batch selected for blending shall be manufactured using similar process, individually tested and found to meet specifications prior to blending.
- ✧ Each blended batch shall have a unique batch number, which shall indicate that it is blended batch. Out-of-Specification batches shall not be blended with other released batches.
- ✧ The batch record of the blending process shall allow traceability of individual batches utilised in the blend.
Blended batch shall be tested for conformance to established release specification.
- ✧ Blending operation shall be validated as per pre-approved protocol.
- ✧ The expiry or retest date of the blended batch shall be based on the manufacturing date of the oldest tailings or batch in the blend.
- ✧ Stability testing shall be performed on blended batch, if assessed by Quality Assurance that blending could adversely affect stability.

AMENDMENT AND WAIVER :

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

DEFINITION :

Blending : A process of combining materials within the same specification to produce a homogeneous API.

ABBREVIATIONS :

API : Active Pharmaceutical Ingredient
ICH : The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

REFERENCES :

ICH Q7 Good Manufacturing Practices Guide for Active Pharmaceutical Ingredient.