## 1 Purpose

The purpose of this guideline is to provide guidance regarding the reworking, reprocessing or recovery (salvaging) of formulated products, active pharmaceutical ingredients (API's) and intermediates used in the processing of APIs.

## 2 Scope and Applicability

This document is applicable to all commercial products manufactured within A manufacturing facility. Products used or manufactured within R&D facilities solely for R&D purposes are excluded. Local or national Regulations may take precedence over this guideline.

## 3 Definitions

### 3.1 Product

Formulated Product, API or API intermediate.

### 3.2 Re-treatment

Re-treatment is the general term applied to any recovery, rework or reprocess activity.

### 3.3 Re-processing

Reprocessing is the act of repeating process step(s) that is (are) part of the established manufacturing process for product.

Note:
For formulated product reprocessing is carried out on product of unacceptable quality so that its quality may be rendered acceptable. For APIs and intermediates reprocessing can also be carried out on product that meets established specifications e.g. in order to combine smaller amounts.

### 3.4 Reworking

Reworking is subjecting all or part of a batch of product that does not conform to standards or specifications to one or more processing steps that are different from the established manufacturing process to obtain an acceptable quality product.

### 3.5 Recovery

Recovery is the introduction of all or part of previous batches of the required quality into another batch at a defined stage of manufacture.

Note:

 

constitution of the product (e.g. slugging and recompressing, milling and blending with new manufacture, adding extra lubricant, recoating) is not permitted.

## 5.7 Capsule Products

Similar principles to tablet products, section 5.5, should be applied. Retreatment activities that do not alter the physical constitution include metal checking, check weighing, hand picking and polishing.

## 5.8 Liquid/Cream Products

Due to physical stability problems, any retreatment of creams or other emulsions should occur within 24 hours of the original processing.

If the retreatment involves the remixing and/or refiltering of a simple mixture then additional testing after that stage will usually be sufficient.

When a cream or other emulsion requires remixing, usually with a reheat and cool process then some stability testing should be performed on the retreated product. This also applies to re-homogenization processes.

If additional active agents or excipients have been subsequently added to correct an error then additional sampling/testing for the component(s) added must be undertaken. If remixing, re-homogenization etc. are required following the addition then stability testing may be required, as described above.

Packed material is sometimes recovered by re-bulking and refilling. In this case, additional tests for active agent uniformity in the refilled packs should be carried out. If remixing, re-homogenisation etc. has been necessary then stability testing may be required, as described above.

Recovery of batch residues from these formulations must not be carried out.

## 5.9 Sterile Products/Inhalation Products

The only retreatments allowable are:

(i) Re-inspection of ampoules/vials if the material has failed for particulate contamination. Sampling/testing should be increased for the re-inspected batch, according to a defined statistical plan.

(ii) Re-filtration of the bulk solution when filters fail bubble-point tests or other abnormality has occurred during filtration.

Testing must be performed to establish that re-filtration has not resulted in an adverse effect from interaction with filter materials, particularly on active agent and preservative levels.

 