

the reprocessing operation.

### **5.1.6 Stability**

Formal stability studies shall be conducted for API's. Data from ongoing studies can be used to extend initial retest periods. Stability studies may be undertaken by the company itself or at a contractor, or a vendor as appropriate / registered.

### **5.1.7 Changes to Initial Retest Periods**

Permanent extensions to assigned initial retest periods may be made where satisfactory evidence is available to support the changes. For an API such evidence is typically data from stability programs but may also include real time testing of material in stock. Any change must be made via the change management system in order that it is subject to regulatory compliance and to ensure that all relevant documents and systems are updated.

## **5.2 Excipients, Intermediates and Raw Materials**

### **5.2.1 Retest Dating and Initial Retest Periods**

Retest dating and the use of retest periods is the standard method of controlling the use of these materials.

Excipients and Raw Materials shall be assigned an indicative initial retest period and retest date based upon available data on a case by case basis. The initial retest date shall be determined by :-

1. The retest date assigned by the vendor (either stamped on the container or indicated on the certificate of analysis), assuming storage conditions at the vendor are comparable with those at the receiving site, and that the company specification is comparable with the vendor's specification.
2. Where available, stability determined by the company or stability data provided by the vendor (where a retest date is not provided by the vendor on the label or on the Certificate of Analysis).
3. Examination (e.g. analysis, user trials, etc) of samples from stock of several batches of similar age.

For intermediates a one-off stability study is typically used to determine the initial retest period.

The retest date shall be calculated from the date of manufacture of the material if available.

For raw materials and excipients where a date of manufacture is not available from the supplier, the date of testing or date of release on the Certificate of Analysis may be used. For non-certified materials, the date of receipt at the site may also be used.

Once any material has reached its retest date, the material shall not be used until