

# Standard Operating Procedure

## Title: Retest Dating of Raw Materials

LAB-055	Laboratory Results-OOS Investigation
LAB-060	Raw Materials-Laboratory Testing and Documentation

### EHS Statement

There is no EHS impact as this is a documentation process.

### Table of Contents

1.	Expired Stock Report.....	2
2.	Raw Materials Approaching their Retest Date .....	2
3.	Non Chemical Considerations for Raw Material Retesting .....	3
4.	Chemical Considerations in Raw Material Retesting .....	3
5.	Retesting of Raw Material .....	4
6.	Use of Raw Material Before Retesting .....	5
7.	Documentation of Retest Period .....	5
8.	Changes to Initial Retest Periods .....	6
9.	Use of Raw Materials Greater than 5 Years of Age .....	6
10.	Summary of Changes.....	6

### Procedure

#### 1. Expired Stock Report

- 1.1. The Laboratory Manager or delegate at the beginning of each month will run the “Finished Goods Batches with Impending Expiry” report, which includes both raw materials and finished goods. The report includes Product/Raw Material code, Description, BPN/Lab. number, Location number, quantity, Value of Item and Expiry date. This procedure is outlined below.
- 1.2. RAW MATERIALS –include Active Ingredients, excipients and intermediates. Retesting is performed to extend the shelf life. These have a maximum initial retest period of X years providing supporting stability data is available.
- 1.3. FINISHED GOODS – This includes both local, imported and contract finished goods. They are rejected if past minimum Expiry Date and not sold.

#### 2. Raw Materials Approaching their Retest Date

- 2.1. All chemical Raw Materials used in products bear a date (Retest Date) after which they may not be used in a batch without further testing. Once the Raw Material has reached its retest date, it may be retested and a new retest period assigned.
- 2.2. The retest date for a raw material and testing regime required for retesting is determined from the relevant Raw Material Specification – Test Report document (e.g. RM-XXX-YY.A). See SOP QMS-030 & TEM-005.
- 2.3. A retest date is determined by:

# Standard Operating Procedure

## Title: Retest Dating of Raw Materials

---

- 5.3.2. The Quality Assurance Manager or the Laboratory Manager must be advised immediately of any test during the re-examination that fails to comply with the Raw Material Specification. This may necessitate a reduction in the shelf life for the material and/or placing finished good batches made with it under **Quarantine** until a firm decision is made.
- 5.3.3. If the Raw Material subsequently fails testing it is to be rejected and all batches in which it was used will be referred to the Quality Assurance Manager for evaluation.
- 5.3.4. If the Raw Material is to be rejected due to reasons described in section 3 and 4 or the Raw Material fails retesting, the raw material is given a FAIL status on **Form-335**.
- 5.3.5. The Laboratory manager raises a Deviation Report (see SOP **QMS-035**) which is noted on **Form-335** and also informs the planner/buyer to ensure that potential disruptions to production scheduling are minimised.

## 6. Use of Raw Material Before Retesting

- 6.1. If a Raw Material has to be used after its expiry date, but before a new expiry date has been assigned, a Deviation Report must be raised (see SOP **QMS-035**) outlining justification of why the raw material may be used. Consideration should be given to Section 7. Approval must be sought from the Laboratory Manager before the Raw Material is used in production.
- 6.2. The finished good batch must also be placed on the Stability Data program.

## 7. Documentation of Retest Period

The rationale used to determine the retest period shall be documented. The approval shall:

- 7.1. Avoid "1 batch testing".
- 7.2. To assure continued stability and avoid one batch testing, a stability profile of the active can be built up using extended stability products. Where stability limited stability data is available, further supporting data can be obtained such as analysis of samples from stock of batches of similar age and an evaluation comparing impurity levels and profiles with original results.
- 7.3. Evaluate the effect of ageing on the physical parameters of the material.
- 7.4. Consider final usage form of the product.
- 7.5. Consider the conditions in which the active has been stored.
- 7.6. Consider the Regulatory implications.