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.

8. Changes to Initial Retest Periods