5.2.2 Reporting and Documentation

5.2.2.1 Reporting

1. Copies of the final OOS Investigation Report are distributed to the appropriate Quality management.
2. Preliminary assessment should be done within 2 working days (refer to attachment 1 Section I).
3. Complete investigation should be closed within 30 calendar days (refer to attachment 1 Section II to III).
4. For stability samples the timing for FDA Field Alert Reporting begins with the discovering the OOS result (these must be reported to the FDA within 3 working 24 hour periods after discovery of the result). For those products that are the subject of applications, regulations require submitting within three working days a field alert report (FAR) of information concerning any failure of a distributed batch to meet any of the specifications established in an application. For more details refer to SOP NDA Field alterts.
5. In the event of a confirmed failure (OOS result), notify all other appropriate parties via deviation procedure SOPs formsheet. For more details refer to SOP Deviations.

5.2.2.2 Documentation

1. All results including rejected data will be retained in laboratory records. A complete description of the reason for rejection will be included in the QC analyst's records with the signatures of both the QC analyst and QC supervisor.
2. All results from the original and repeat testing will be used for calculation of the final test result except for results that are invalid due to identified laboratory error.
3. The investigation report will be uniquely numbered to permit tracking and measurement of performance.
4. The original signed OOS Investigation Report is maintained in a controlled and retrievable manner in the QC laboratory.

6. Definitions

Out of Specification (OOS) Result:
A (reportable) result that falls outside established acceptance criteria.

Repeat(ed) testing:
Performing the testing (a new) as described in the control test. Only allowed if former results can be invalidated.

Retest:
Repeating the whole testing on a different portion of the same sample.

Control Sample:
A sample of material that has been previously tested and approved or is well characterized.