1. PURPOSE

The FDA requires that an investigation be conducted whenever an Out-of-Specification (OOS) result is observed. This SOP defines the requirements for dealing with failed test results.

2. SCOPE

Laboratories generating test results that are used to reject raw materials or to release finished products or active pharmaceutical ingredients. The SOP can be employed for OOS results and for suspect test results.

3. GLOSSARY/DEFINITIONS

Item	Explanation
OOS	Out-of-Specification. OOS results include those that fall outside the specifications or acceptance criteria established in New Drug Applications (NDAs), official compendia or by the manufacturer.
Suspect Results	Test results that fall outside historical, expected or previous trends.
Retesting	Repeated testing of a portion of the original sample. The sample is taken from the same homogeneous material used for the original test.
Resampling	Collection and testing of a new sample from the batch. Resampling is conducted if the investigation concludes that the original sample was prepared improperly and was therefore not representative for the batch.

Note: For other definitions, see www.labcompliance.com/glossary.

4. REFERENCE DOCUMENTS

4.1. FDA Guidance for Industry: “Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production”, draft, 1998.

7.16. Investigation reports should include: steps taken, raw data, supporting documents, findings and explanations, conclusions and recommendations to avoid occurrence of similar deviations in the laboratory.

7.17. The investigation report is reviewed and approved by the laboratory supervisor and QA.