STANDARD OPERATING PROCEDURE

Title: QC Test Failure, Repetition and Investigation Rules

Effective Date: _____

Approvals (Signature and Date):

_____	_____	_____
Responsible Department Head	Technical Authority	QA/QC

1. PURPOSE

1.1 To describe a method for addressing out-of-specification quality testing results.

2. SCOPE

2.1 This procedure applies to lot release testing performed by QC personnel on product or components made by Manufacturing.

2.2 This procedure applies to testing performed by QA/QC personnel in support of stability studies on final products.

2.3 This procedure applies to testing performed by QC personnel on raw materials procured from outside vendors.

2.4 This procedure does not apply to environmental monitoring performed in company facility, or to other monitoring of facilities and utilities.

3. RESPONSIBILITY

3.1 It is the responsibility of QA/QC analysts performing quality testing to notify supervisor and to follow the stated rules for repetition of testing following an "out-of-specification" result.

3.2 It is the responsibility of the QC Supervisor in conjuction with the analyst to perform initial investigation on "out-of-specification" quality test results.

3.3 It is the responsibility of the QA/QC Head to manage the investigation of "out-of-specification" quality test results so that it is documented and completed prior to material disposition.

4. REFERENCES AND APPLICABLE DOCUMENTS

4.1 Quality Control Reports "The Gold Sheet", Vol. 27, No. 2, February 1993.

4.2 FDA Guide to Inspections of Pharmaceutical Quality Control Laboratories, July 1993

4.3 09-0004-SOP-1.0, Discrepancy Report Procedure

5. MATERIALS AND EQUIPMENT

5.1 All QC testing equipment required for applicable testing.

6. HEALTH AND SAFETY CONSIDERATIONS

6.1 Use safety precautions applicable for specific test being performed.

7. DOCUMENTATION REQUIREMENTS

7.1 QC Test Failure Reporting Form, Attachment A

7.2 QC Test Failure Log, Attachment B

7.3 QC Inspection Services Request and Lot Summary, attachment to PNS

7.4 Discrepancy Report, attachment to 09-0004-SOP-1.0

8. GENERAL PROCEDURAL REQUIREMENTS AND INTRODUCTION

8.1 Quality test failure is defined as an out-of-specification (OOS) result on a test performed by a QA/QC analyst.

8.2 Quality test failures must be investigated and explained using reasonable and scientific rationale and appropriate data.

8.3 "Out-of-specification" quality test results may not be discounted or discarded without appropriate investigation.

8.4 Repeat of quality testing and/or resampling of product may not occur until QC Supervisor has been notified of test failure.

8.5 Retesting of product following a quality test failure is used to determine validity of results, and is appropriate only when following the rules stated in this procedure. Product may never be "tested into compliance" using repeated retests.

8.6 Following appropriate investigation and explanation, only values accepted as valid test results are recorded on the QC Inspection Services Request and Lot Summary form ("Pink Sheet"). All related data and investigation documentation must be included in lot file or receiving inspection report.

8.7 In general, investigations of OOS quality test results should include review of prior production records to determine if the situation has occurred in the past. The investigation should also review the manufacturing process to determine if any unusual events occurred during the production of the product being tested. Additionally, the method, materials, procedure and related documentation used by QA/QC personnel must be reviewed as part of the investigation procedure.

8.8 Investigation of quality test failures must be documented using a QC Test Failure Reporting Form, Attachment A. Each time use of QC Test Failure Reporting Form is initiated, the event must be logged in and assigned a number on Attachment B, QC Test Failure Log. The investigation must be completed and must be approved by the QC Supervisor and QA/QC Head prior to material disposition.

9. PROCEDURE

9.1 Product or component is tested using appropriate methods described in PNS.

9.2 The initial "out-of-specification" result (OOS) must be reported to the QC Supervisor.

9.3 The QC Supervisor and analyst must then conduct an "informal" laboratory inspection which includes a review of the test data, a discussion of the testing procedure along with any required calculations, examination of reagents and other related test materials used to perform procedure, review of documentation containing OOS results, and an examination of the instrument used.

9.3.1 At this time, any suspected or obvious conditions can be corrected. For example, expired or contaminated reagents can be replaced and uncalibrated or malfunctioning equipment can be calibrated or repaired as necessary.

9.3.2 Retesting is appropriate if analyst error is a possible cause or when an informal investigation is inconclusive.