1.0 Purpose

The purpose of this procedure is to give guidelines and requirements on sending samples to an external testing laboratory.

2.0 Scope

This procedure applies to all raw materials, finished products, stability, reference standards and investigative samples sent to an external laboratory for testing.

3.0 Responsibility

3.1 It is the primary responsibility of the QC Laboratory personnel to send raw materials, finished product, stability, reference standards and investigative samples for external testing.

3.2 It is the responsibility of QC Laboratory Management to implement this procedure and to ensure that the procedure is being followed.

3.3 It is the responsibility of Quality to complete vendor qualifications.

3.4 It is the responsibility of QC Laboratory Management to keep the SOP current with latest Ion Labs practices.

4.0 Definitions

4.1 **CofA** - Certificate of Analysis

4.2 **QC** – Quality Control

4.3 **DC** – Document Control

4.4 **USP** – United States Pharmacopeia

4.5 **ISO** – International Organization of Standardization

4.6 **ISO/IEC 17025** – General requirements for the competence of testing and calibration

laboratories is the main ISO standard used by testing and calibration laboratories. Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to produce valid results. It is also the basis for accreditation from an accreditation body.

5.0 References

5.1 E-601, SOP, Vendor Qualification

5.2 E-601-F1, Form, Vendor Questionnaire

6.0 Procedure

6.1 This procedure defines the steps needed for outsourcing any laboratory release testing. Reasons for outsourcing laboratory testing include

6.1.1 Equipment needed not available in-house.

6.1.2 Internal method not validated.

6.1.3 Laboratory capacity exceeded.

6.2 Before shipping a raw material, finished product, stability, reference standard or investigative sample for outside laboratory testing, QC Laboratory personnel must verify that the external lab that is intended for receipt of the samples is a qualified laboratory. The current Approved Vendor List is available at F:\Shared Files\Approved Vendor List.

6.3 Selecting the appropriate outside laboratory should also be based on the testing required.

6.4 In addition to confirming the contract laboratory is an approved laboratory, the contract laboratory must be accredited to the specification, standard method of technique used. (All outsourced testing for ISO 17025 accredited testing must be completed by vendors that are ISO 17025 certified)

6.4.1 ISO 17025 accreditation for testing required must be present.

6.4.2 If ISO 17025 accreditation is not present, Ion Labs may perform an on-site audit of the prospective contract laboratory to grant approval.

6.4.3 The on-site audit report will be forwarded to the Quality Unit for review and final outside laboratory approval.

6.5 Care should be taken when shipping a sample to an outside laboratory. Any special

storage conditions for the sample must be considered for shipment. In addition, Ion Labs personnel should take care to not share any proprietary/ confidential information with the contract laboratory if possible.

6.6 If an OOS result is observed at a contract laboratory and the result was confirmed to not be laboratory related, an OOS per SOP D-105 must be initiated. The outside laboratory may be directed to perform investigational re-tests per the internally initiated investigation. All results and protocols should be captured as if the OOS occurred internally.

6.7 Reporting of results by the contract laboratory should be per a Certificate of Analysis. These results will then be transferred to Ion Labs testing documentation. All copies of C of A's will be included with testing packet. (All outsourced ISO accredited testing reported to customers will be identified on the Test Report as such.)

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/03/10	New	-	-
1	02/21/13	Implemented new format for SOP's, removed PO# requirement.	-	-
2	10/08/13	Added R&D responsibilities for raw material outsourced testing, added information on how R&D manages and tracks test data, removed Form D-202-F2	13-883	B. Johns
3	01/20/15	Expanded responsibilities to reflect new hierarchy. Transferred R&D responsibilities to the QC Technical Coordinator. Clarified documentation of raw material external testing.	15-0022	B. Johns
4	04/05/17	Converted logs to electronic format. Added tracking log for pharmaceutical raw materials. Removed paper log format. Changed responsibilities.	17-0356	B. Johns
5	10/17/19	Complete re-write to follow updated process.	19-0759	J. Sassman
6	11/04/21	Added ISO 17025:2017 Requirements. Fixed numbering.	CC-21-0415	J. Sassman