

	Standard Operating Procedure Raw Material Life Cycle and CoA Challenge Process		SOP Number D-901	Revision 8	
			Effective Date 01-08-20	Page Page 1 of 8	
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1.0 Purpose

The purpose of this SOP is to describe the lifecycle of a raw material including creation of a record in BatchMaster, creation/revision of the Raw Material Profile, testing, release, and CoA challenge process.

2.0 Scope

This procedure applies to all incoming raw materials at Ion Labs. This procedure does not apply to the logging of raw material samples, investigating OOS results, the post-QC Lab raw material release process, the recertification of expired raw materials, or to the reassignment of a raw material to an alternate RMID.

3.0 Responsibility

- 3.1 It is the responsibility of Purchasing to source appropriate raw materials.
- 3.2 R&D is responsible for creating records in BatchMaster for new raw materials.
- 3.3 It is the responsibility of Purchasing to place purchase orders for RMs and to obtain the CoA for each material ordered.
- 3.4 The QC Laboratory and R&D are responsible for approving raw materials, selecting the required testing, and generating the Raw Material Profile for each unique raw material.
- 3.5 The QC Laboratory is responsible for setting specifications with assistance from R&D.
- 3.6 It is the responsibility of the Warehouse to add the R# specific raw material information into Batchmaster.
- 3.7 It is the responsibility of QC Samplers to deliver the appropriate RM samples to the QC Laboratory.
- 3.8 The QC Laboratory is responsible for release testing, coordinating external laboratory testing, documenting the results of such testing, reviewing the final data, and submitting the results to DC for release of the raw material.
- 3.9 It is the responsibility of DC to maintain all original Raw Material Profiles and the QRM List.

400 Definitions

- 411 APML = Approved Product Material List
- 422 CoA * = Certificate of Analysis
- 433 DC = Document Control
- 444 LOD = Loss on Drying
- 455 OOS = Out of Specification
- 466 ~~OTC~~ Over the Counter
- 477 QC = Quality Control
- 488 QRM List = Qualified Raw Material List; electronic spreadsheet maintained by DC which lists all RMs that have passed the CoA Challenge process.
- 499 R# = A unique identifying number assigned to raw materials upon receipt
- 410 R&D = Research and Development
- 411 RM = Raw Material
- 4112 ~~RMID~~ Raw Material Identification
- 4113 RMTS = Raw Material Testing Summary

500 References

- 511 C-201, SOP, Deviation and Investigation Procedure
- 522 C-403, SOP, Change Control Procedure
- 533 C-601, SOP, New Product Approval Process
- 544 D-105, SOP, Out of Specification/Out of Trend Investigation
- 555 D-109, SOP, Qualitative Standards
- 566 D-902, SOP, Establishment of Specifications
- 577 E-601, SOP, Vendor Qualification

600 Raw Material Manufacturer Selection Process

- 611 Raw material manufacturer selection is led by Purchasing and approved by R&D as part of the formulation process.
- 622 Before a raw material intended for a pharmaceutical formulation can be purchased, the manufacturer should be qualified by QA.
- 633 Before a material is purchased for a pharmaceutical formulation, the CoA of each lot should be reviewed and approved by QC.

Generation of a New Raw Material Identification Number

- 7.11 During the formulation process, R&D identifies new raw materials and generates RMIDs in BatchMaster.
- 7.22 A raw material ID number will be assigned to the raw material. The ID number will consist of two parts (e.g. RMS000001):
- 7.22.1 Use type designator consisting of three letters.
 - 7.22.1.1 RMS indicates intent for use in a dietary supplement.
 - 7.22.1.2 RMD indicates intent for use in a drug product.
 - 7.22.1.3 RMC indicates intent for use in a cosmetic product.
 - 7.22.1.4 RMP indicates intent for use in a pet product.
 - 7.22.1.5 RMF indicates intent for use in a food product.
 - 7.22.2 The use type designator is followed by a six digit sequential number.
- 7.33 R&D will define the naming for the raw material as follows:
- 7.33.1 The naming schemes defined herein are general guidelines. All elements listed below may not be applicable to all raw materials.
 - 7.33.2 Fine chemicals or defined chemical composites
 - 7.33.2.1 Common name
 - 7.33.2.2 Trademarked name
 - 7.33.2.3 Concentration
 - 7.33.3 Botanicals
 - 7.33.3.1 Common name
 - 7.33.3.2 Scientific name
 - 7.33.3.3 Plant part
 - 7.33.3.4 Extract ratio or standardized concentration
 - 7.33.3.5 Other critical designators (e.g. organic)

8.0 Raw Material Profile Creation

- 8.1 After R&D creates a new RMID in BatchMaster, the critical and preferred physical characteristics of the material will be provided to the QC Lab as needed.
- 8.2 R&D designates any required or inherent properties of the RM (e.g. gluten free, non-GMO, vegetarian)

- 8.3 The Raw Material Profile will be created by the Q&C Laboratory with input from R&D and the information entered into BatchMaster.
- 8.4 The Raw Material Profile, which is divided into Release Specifications, Sampling Requirements, and Purchasing Specifications, contains the following information:
- 8.4.1 Document Header (same for each section)
- 8.4.1.1 Raw Material Name (as documented in the Raw Material Database)
 - 8.4.1.2 RMID
 - 8.4.1.3 Material Category (Botanical, Drug, Fine Chemical, etc.)
 - 8.4.1.4 Approved for use in designations (OTC, Human, Cosmetic, etc.)
 - 8.4.1.5 Warnings (Allergen, Hygroscopic, etc.)
- 8.4.2 Release Specifications are determined based on number of factors including regulatory requirements, use class, label claims, and customer requirements. The procedure for establishment of specifications is outlined in D-902.
- 8.4.3 Purchasing Specifications
- 8.4.3.1 For the required testing listed under Release Specifications (Section 8.4.2), tests that are critical to product performance are listed to assist purchasing in sourcing the raw material.
 - 8.4.3.2 For each critical test, a critical value is listed for which any raw material purchased must satisfy.
 - 8.4.3.3 For each critical test, a preferred value may be listed which indicates the desirable value for raw material purchasing.
- 8.4.4 Sampling Requirements
- 8.4.4.1 For each test or group of tests, the amount of sample required to complete the test(s) is listed.
 - 8.4.4.2 Two sample amounts are listed, The first is the amount required to perform all testing included in a CoA challenge, while the second is the amount required to perform the reduced testing required after CoA challenge has been completed.
 - 8.4.4.3 Q&C Work Order number.
 - 8.4.4.4 R number.
 - 8.4.4.5 Bin number.
 - 8.4.4.6 Delivered to Lab By.
 - 8.4.4.7 Date/Time Delivered.

~~8.4.4.8~~ Prepared By/Date.

~~8.4.4.9~~ R&D Reviewed By/Date.

~~8.4.4.10~~ QC Lab Reviewed By/Date.

~~8.4.4.11~~ Quality Approved By/Date.

8.5 The RMTS is generated along with the RM Profile and includes the following information:

8.5.1 Name of Raw Material and ID#

8.5.2 Name of the Manufacturer or Distributor

8.5.3 Receiving Number (R-Number)

8.5.4 Date Received

8.5.5 Vendor Lot Number

8.5.6 Expiration Date

~~8.5.6.1~~ Upon successful completion of the CofA, challenge process an expiration date is assigned to the raw material lot number and entered into BatchMaster.

~~8.5.6.2~~ If the manufacturer CoA gives an expiration/retest date for the material then that date is used.

~~8.5.6.3~~ If the manufacturer expiration date is less than one year from date of receipt and a full CofA challenge is completed for release then the expiration date can be increased up to one year from date of release. Flavorings are typically extended no more than 30 to 90 days.

~~8.5.6.4~~ If no manufacturer expiration date is listed on the CofA, but the date of manufacture is listed, then the raw material can be assigned an expiration date for up to three years from the date of manufacture at the discretion of QC Management.

~~8.5.6.5~~ After the expiration date, the material can be CofA challenged again as per D-303. Upon successful completion of the challenge, the material expiration can be extended up to one year at the discretion of QC management.

~~8.5.6.5.1~~ When the raw material is released the QC Laboratory will enter the new raw material expiration into BatchMaster. The R# and a dash # will be used to identify the number of times a material has been recertified. A raw material cannot be recertified more than three times.

8.5.7 Required Testing

8.5.8 Required Method(s)

8.5.9 Release Specification

8.5.10 A space for entry of the testing result,

8.5.11 A space to indicate whether the required testing passed or failed.

8.5.12 Initials/Date of the person entering the data.

8.5.13 Initials/Date of the person confirming the accuracy and completeness of the data.

8.5.14 If no expiration date is available, assign a default date of 12 months for stable chemicals and 3 months for flavorings. Other expiration dates may be used with scientific justification. If material is unstable, QC Laboratory management will determine a suitable expiration date based on applicable literature.

8.6 Once reviewed and approved, DC will maintain the original copy of the RM Profile for each RMID. A scan of the approved RM Profile will be stored in a shared file directory.

9.0 Revision of a Raw Material Profile

9.1 A Change Control Request is not required for new RM Profile documents.

9.2 Revisions to existing RM Profiles will be conducted through the Change Control process as outlined in SOP C-403.

10.0 Raw Material CoA Challenge Requirements

10.1 The RM CoA Challenge process is included as part of the Vendor Qualification procedure per SOP E-601.

10.2 CoA Challenge status of incoming material will be determined by the QC Lab, communicated to the QC Samplers, and documented on Form D-901-F1, Raw Material Testing Summary (RMTS).

10.3 A minimum of three unique lots per manufacturer must be challenged before the manufacturer is qualified.

10.4 After the manufacturer is qualified to supply the raw material, a minimum of identification is required for release.

10.5 If a RM is received and does not meet specifications, the CoA challenge should be repeated.

10.6 If the supplier is undergoing increased regulatory scrutiny, the CoA challenge should be repeated.

110.7 Data generated during re-certification testing of a RM per SOP D-303 are not valid for inclusion in the CoA Challenge process.

110.8 Once the full CoA challenge process is complete for a raw material / manufacturer combination, an unabbreviated CoA challenge is required on the first lot after a twelve month period from the date of completion of the last CoA challenge. Depending on the frequency of raw material purchases from a manufacturer, full CoA challenges can be initiated at a greater frequency. Increased frequency of CoA challenges is determined by QCC Management.

11100 CoA Approval, Testing, and Release of Raw Materials

111.1 Purchasing will submit a copy of the manufacturer's CoA to QCC lab for approval. Approvals are based on requirements outlined in the RM Profile. If the RM has not been previously purchased from the manufacturer, the purchase should also be approved by R&D.

111.2 Testing is performed as directed in the RM Profile based on the CoA Challenge Status.

111.3 If a RM does not meet a specification listed in the RM Profile, the material can be rejected and returned to the vendor.

111.4 The completed and approved RMTS and manufacturer's CoA are submitted to DC for archiving.

11200 Use of Raw Materials in Production

112.1 RMs should be released by Quality prior to use in Production.

112.2 For dietary supplements, pet products, and cosmetics, RMs may be used in Production at risk; however, all RM testing must be completed and RMs released prior to release of the FP.

112.3 Additional testing requirements may be stipulated prior to QCC Lab clearance of an RM based on RM vendor, risk, product, client request, etc.

11300 Release of Raw Materials

113.1 After all testing has been successfully completed, the manufacturer CoA and all associated data are combined into one packet and submitted to DC for archiving.

113.2 After all testing has been completed successfully, the QCC Lab will update the RM status in batch master to "released".

11400 Attachments

114.1 Attachment 1 = Example Document: Raw Material Profile

15.0 Revision History

Revision	Date	Description of Changes	CCN	By
0	08/30/10	New	-	-
1	10/17/12	Updated R&D process. Added forms. Changed SOP title and format.	-	-
2	06/17/13	Removed RMITC. Removed R&D formulation section. Removed sections 6.0 and 7.0. Updated process for RMSTT.	13-451	V. Itcheva
3	03/28/14	Updated format. Added information on test selection and specification selection. Removed information regarding standard selection and referenced SOP D-109. Referenced D-202 for external lab testing.	14-0280	B. Johns
4	01/05/16	Combined information from SOPs D-302, D-901, and E-602. Updated out of date information with present practices.	16-0021	N. Zhang
5	06/15/16	Addition of Cosmetics criteria to SOP. Updated RM challenge requirements.	16-0422	B. Johns
6	10/23/17	Sections 7.3.1 and 9.1-Added a separate entry on the RMSTT for Manufacturer. RMSTT format is updated to reflect this change.	17-1318	S. Barnes
7	01/02/18	Rewrite of SOP to reflect new procedure using Raw Material Profiles.	18-0008	S. Barnes
8	03/04/20	Remove references to SOPs that are now obsolete. Add references to new SOPs that are relevant. Update for consistency with current practices.	CC-20-0259	S. Sassman