

	Standard Operating Procedure	SOP Number D-303	Revision 5
	<b>Recertification of Raw Materials</b>	Effective Date 03/06/24	Page Page 1 of 5
Written by/ Date <i>SS 01/05/24</i>	Reviewed by/ Date <i>KB 01/05/24</i>	Approved by/ Date <i>[Signature] 01-08-24</i>	
Title: Quality Control Director	Title: Quality Assurance Director	Title: VP of Quality & Regulatory Affairs	

## 1.0 Purpose

The purpose of this procedure is to outline the process of identifying expiring raw materials, material handling and the recertification of an expired raw material to ensure material quality when extending the expiration date.

## 2.0 Scope

This procedure applies to all raw materials intended for use in finished products at Ion Nutritional Labs.

## 3.0 Responsibility

- 3.1 It is the responsibility of Finance or designee to run a monthly (or as needed) report and to identify all expiring raw materials.
- 3.2 It is the responsibility of the Warehouse to inventory the materials from the report.
- 3.3 It is the responsibility of the QC Laboratory to determine which raw materials are suitable for recertification.
- 3.4 It is the responsibility of Finance to determine which raw materials will be retested and which materials will be disposed of in conjunction with QC Laboratory feedback.
- 3.5 It is the responsibility of QC Samplers to sample raw materials and submit to QC Laboratory for retesting.
- 3.6 It is the responsibility of the QC Laboratory to add recertified raw materials to the material database and to release the recertified raw materials.

<b>Standard Operating Procedure Recertification of Raw Materials</b>	<b>SOP No D-303</b>	<b>Rev 5</b>	<b>Page 2 of 5</b>
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## **4.0 Definitions**

- 4.1 **DC** – Document Control
- 4.2 **QA** – Quality Assurance
- 4.3 **QC** – Quality Control
- 4.4 **CofA** – Certificate of Analysis
- 4.5 **RMTT** – Raw Material Test Ticket
- 4.6 **R#** – A raw material number assigned by Ion Labs
- 4.7 **Shelf life** – the period of time during which a material may be stored and remain suitable for use

## **5.0 References**

- 5.1 E-801, SOP, Return of Materials and Destruction of Non-Hazardous Waste Materials
- 5.2 D-303-F1, Form, Raw Material Recertification Request

## **6.0 Procedure**

- 6.1 Identifying and Handling of Expiring Raw Materials
  - 6.1.1 At the end of each month, or as needed, Finance or designee will generate a report identifying all of the raw materials that are set to expire in the next month or as defined on the report.
  - 6.1.2 This report will be given to the Warehouse for inventory assessment.
    - 6.1.2.1 The Warehouse will locate each expiring raw material and move it to a quarantine area if needed. Raw materials undergoing re-certification

only need to be placed into quarantine if material has passed expiration date.

6.1.2.2 The Warehouse will update the information on the report for expiring materials and return the copy to Finance.

6.2 Finance will review the updated report and send a copy to the QC Laboratory for assessment of the raw materials that are valued for recertification.

6.3 The QC Laboratory will evaluate the potential for recertification based on several criteria to include but not limited to:

6.3.1 Material is within five years old from the date of receipt. For materials over five years a CofA or a letter from the manufacturer must indicate that the material can meet specification beyond this time period.

6.3.2 The quantity of material and it's cost.

6.3.3 The cost of testing.

6.3.4 The material has been recertified less than three times by Ion Labs.

6.4 If a material meets the requirements for retest:

6.4.1 Finance will submit Form D-303-F1 Material Recertification Request to QC Management. Alternatively, re-certification request may be electronically submitted to appropriate departments.

6.4.2 QC Samplers will sample the material and submit to QC laboratory for retesting.

6.4.3 The CofA and RMSTT will be retrieved by the QC Laboratory and the material will be evaluated for critical characteristics with the potential to change and/ or impact the life of the raw material, i.e.

<b>Standard Operating Procedure Recertification of Raw Materials</b>	<b>SOP No D-303</b>	<b>Rev 5</b>	<b>Page 4 of 5</b>
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1. Moisture
2. Microbial contamination
3. Organoleptic
4. Strength (as applicable)

6.4.4 If a material does not meet requirements for retest:

6.4.4.1 Material will be disposed of as per SOP E-801 Return and Destruction of Non-Hazardous Waste Materials.

#### 6.5 Raw Material Shelf-Life Extension (Re-Certification)

6.5.1 Once a raw material is re-certified in the laboratory a new expiration (re-evaluation) date will be established.

6.5.2 This new expiration date will be dependent on the risk of the raw material. Shelf-life information from supplier may be consulted for an extension.

6.5.3 History and purpose of raw material should always be considered when re-certifying.

6.5.4 Shelf-life extension can be up to one year but not to exceed 50% of the original shelf-life period as determined by supplier.

6.5.4.1 For example, a material received with a one year shelf-life can only be extended for a maximum period of six months.

6.5.4.2 For example, a material received with a three year shelf-life can only be extended for a maximum period of one year.

6.6 Retest Results and New Expiration Date:

6.6.1 If the retest results meet specification, the material expiration date may be reset to a future date as determined.

6.7 The QC Laboratory will return the RMSTT containing the retest data to DC for archiving.

## 7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
1	06/11/13	New	13-438	R. Howard
2	02/13/15	Update SOP Format. Complete rewrite to meet current requirements.	15-0191	B. Johns
3	12/07/16	Update SOP to support retesting of raw materials used in all finished product types (dietary, cosmetic, OTC, etc). Added references to relevant OTC SOPs.	16-1122	B. Johns
4	02/04/21	Update to align with current process. Triennial review.	CC-21-0035	J. Sassman
5	01/03/24	Added section to SOP to address shelf-life extension. Removed reference to D-801.0.	CC-23-0618	J. Sassman



### Raw Material Recertification Request

Form: D-303-F1

CCR No. CC-23-0618

Revision: 1

R#		
ID#		
Material Name		Allergen Material <input type="checkbox"/> *
Vendor/Manufacturer		
Manufacturer/Vendor lot #		
Original Receipt Date		
# of Containers Remaining		
Quantity Remaining		
Original Expiration		

\*Place  if applicable

Recertification Needed By (date)	Date of Recertification Completion

Requested By/Date: \_\_\_\_\_

Completed By/Date: \_\_\_\_\_