

	Standard Operating Procedure Organoleptic Analysis		SOP Number D-722	Revision 4
			Effective Date 05-01-20	Page Page 1 of 2
Written by/ Date ftr 04/29/20		Reviewed by/ Date SA5 09/11/20		Approved by/ Date S. Groth 12/20
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1.0 Purpose

The purpose of this SOP is to define the test method for the organoleptic analysis of raw materials and finished products.

2.0 Scope

This SOP applies to all raw materials and finished products produced in Ion Labs.

3.0 Responsibility

- 3.1 It is the responsibility of trained QC Personnel to follow this procedure.
- 3.2 It is the responsibility of the QC Laboratory Management to implement this procedure and to ensure that the procedure is being followed.
- 3.3 It is the responsibility of the QC Laboratory/Analytical Development Personnel to keep the SOP current with latest Ion Labs practices.

4.0 Definitions

- 4.1 **Organoleptic** = being, affecting, or relating to qualities (as taste, color, odor, and feel) of a substance that stimulate the sense organs.
- 4.2 **QC** = Quality Control
- 4.3 **MSDS** = Material Safety Data Sheet

5.0 References

- 5.1 Merck Index
- 5.2 United States Pharmacopeia
- 5.3 D-901-F1: Raw Material Test Ticket
- 5.4 D-401-F2-FXXX: Finished Product Test Ticket
- 5.5 D-722-F1: Organoleptic Identification Testing Results

6.0 Procedure

- 6.1 Uncommon raw materials that may require organoleptic as a component of the identification process must have a sufficient description for identification on the associated raw material test ticket (D-901-F1), finished product test ticket (D-401) or Product Profile.
- 6.1.1 For materials that do not have organoleptic specifications set, physical descriptions may be found in resources such as the USP, Merck index or other reference.
- 6.2 When safety specifications are unknown for the material being tested it is recommended that the MSDS be reviewed for each material prior to opening and testing the material.
- 6.3 The test begins by first looking at the material within the sample container. If sample container is not clear or the nature of the test requires that the sample be removed, be sure that the removal is done safely (i.e. use protective equipment for strong smelling raw materials or corrosive materials). The material must match the visual description on the test ticket or product profile before proceeding.
- 6.4 If required, smell the samples by opening the container away from the nose and waft the aroma using gentle hand movements. The sample must be free of objectionable odors not characteristic of the material. It may have a characteristic odor that can be confirmed.
- 6.5 Taste samples only if taste is a specified characteristic and the sample is known to be safe as per the MSDS. The sample must be free of objectionable tastes not characteristic of the material. It may have a characteristic taste that can be confirmed.
- 6.6 Record organoleptic results onto D-722-F1 if results are not recorded elsewhere.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	01/20/12	New	-	-
1	12/12/12	Changed SOP format and title, changes in Section 1.0, 2.0, 3.0. Added finished products in section 1.0, 2.0, 5.1.	12-235	B. Johns
2	02/06/15	New SOP format. Adjusted organoleptic to be a supporting ID test, not a primary ID test. Expanded descriptions. Added references D-401-F2 and D-901-F1.	15-0142	B. Johns
3	01/08/17	Revised scope to include all raw materials and finished product manufactured at Ion Labs.	17-0008	N. Zhang
4	04/14/20	Added safety considerations and updated responsibilities	CC-2019272	J. Maignan