

Status: Currently Official on 15-Feb-2025
 Official Date: Official as of 01-Jun-2021
 Document Type: Dietary Supplement Monographs
 DocId: GUID-AE318758-7B52-47A6-B71F-39DE096DAB0A_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M34688_04_01
 DOI Ref: k37ol

© 2025 USPC
 Do not distribute

Garlic Fluidextract

DEFINITION

Garlic Fluidextract is prepared as follows. Soak 1000 g of Garlic, whole or sliced, in a volume of a mixture of water and alcohol (between 80:20 and 50:50) sufficient to cover the cloves. Store in a suitable container for a length of time sufficient to extract the constituents, avoiding any contamination, and then filter. Concentrate the filtrate, if necessary, at the lowest possible temperature, and add sufficient water or alcohol to make the product measure 1000 mL. [NOTE—Complete extraction may require 30 days.]

IDENTIFICATION

• A. THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST

Extraction column: Use a solid-phase extraction column that contains benzenesulfonylpropyl bonded to silica gel in the hydrogen form having a sorbent mass-to-column volume ratio of 1 g per 6 mL, or equivalent. Condition the column before use by washing with 10 mL of methanol and 10 mL of water. [NOTE—Do not allow the column to dry.]

Standard solution: 0.5 mg/mL of [USP S-Allyl-L-cysteine RS](#) in a mixture of methanol and water (1:1)

Sample solution: Mix 1 mL of Fluidextract and 5 mL of water, and transfer to the *Extraction column*. Allow to drain, and discard the eluate. Wash the column with 10 mL of water and 10 mL of methanol, discarding the eluates. Elute the amino acid fraction with 3 mL of ammonium hydroxide solution in methanol (7 in 100), and collect the eluate.

Adsorbent: 0.25-mm layer of chromatographic silica gel, typically 20 cm long (TLC plates)

Application volume: 5 µL

Developing solvent system: Ethyl acetate, methanol, acetone, glacial acetic acid, and water (10:4:3:1:3)

Spray reagent: Iodoplatinate TS

Analysis

Samples: *Standard solution* and *Sample solution*

Develop the chromatograms until the solvent front has moved up about three-fourths of the plate, in a saturated chamber. Remove the plate, and allow the solvent to evaporate. Spray with the *Spray reagent*, and examine the plate.

Acceptance criteria: The chromatogram of the *Sample solution* exhibits, among several yellow spots on the purple plate, a yellow spot at an R_F value of about 0.4 corresponding to that of the yellow spot obtained in the chromatogram of the *Standard solution* (presence of S-allyl-L-cysteine).

COMPOSITION

Change to read:

• CONTENT OF S-ALLYL-L-CYSTEINE

Mobile phase: Transfer 15.8 g of sodium citrate dihydrate to 250 mL of water, and carefully add 10.5 mL of hydrochloric acid. Using a pH meter, adjust with 6 N sodium hydroxide to a pH of 4.0. Dilute with water to 1000 mL, and mix.

Derivatizing reagent: Dissolve 0.8 g of o-phthalaldehyde in 2 mL of 2-mercaptoethanol. Add to a solution containing 24.70 g of boric acid and 22.35 g of potassium hydroxide in 1000 mL of water, and mix.

Reactivating solution: 0.2 N sodium hydroxide. Prepare by dissolving 0.8 g of sodium hydroxide in 100 mL of water.

Standard solution: 0.01 mg/mL of [USP S-Allyl-L-cysteine RS](#) in water

Sample solution: Transfer about 2.0 g of Fluidextract, accurately weighed, to a 100-mL volumetric flask, dilute with trichloroacetic acid solution (5 in 100) to volume, and mix. Centrifuge for 5 min, and filter the supernatant.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: Fluorometric detector; excitation wavelength of 340 nm and emission wavelength of 455 nm

Column: 4.6-mm × 12-cm; packing L17

Column temperature: 40°

Injection size: 10 µL

[NOTE—The *Mobile phase* and the *Reactivating solution* are pumped separately, each at the rate of 0.4 mL/min, by pumps connected to the opposing arms of a tee. The outlet of the tee is connected to the injector and the chromatographic column. The outlet of the column is attached to a tee, the opposing arm of which is attached to a tube from which the *Derivatizing reagent* is constantly pumped through the system at a rate of 0.6 mL/min. The outlet of the tee is connected to a 0.5-mm × 2.0-m postcolumn polytetrafluoroethylene reaction coil maintained at 40°. The outlet of the reaction coil is connected to the detector. The system is programmed to deliver the *Mobile phase* for 10 min, the *Reactivating solution* for the next 6 min, and the *Mobile phase* for the 24 min remaining before the next injection.]

System suitability

Sample: *Standard solution*

Suitability requirements

Capacity factor (k'): 2.5–4.5

Tailing factor: NMT 2.0 for the S-allyl-L-cysteine peak

Relative standard deviation: NMT 2.0% for the S-allyl-L-cysteine peak in repeated injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of S-allyl-L-cysteine ▲▲ (ERR 1-Jun-2021) in the portion of Fluidextract taken:

$$\text{Result} = (r_U/r_S) \times C_S \times (V/W) \times 100$$

r_U = peak height of S-allyl-L-cysteine from the *Sample solution*

r_S = peak height of S-allyl-L-cysteine from the *Standard solution*

C_S = concentration of the [USP S-Allyl-L-cysteine RS](#) in the *Standard solution* (mg/mL)

V = volume of the *Sample solution* (mL)

W = weight of Fluidextract used to prepare the *Sample solution* (mg)

Acceptance criteria: NLT 0.05% on the dried basis

CONTAMINANTS

- [MICROBIAL ENUMERATION TESTS \(2021\)](#): The total aerobic bacterial count does not exceed 10³ cfu/mL, and the total combined molds and yeasts count does not exceed 10² cfu/mL.
- [ABSENCE OF SPECIFIED MICROORGANISMS \(2022\)](#): Meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*

SPECIFIC TESTS

- **RESIDUE ON EVAPORATION:** Proceed as directed under [Botanical Extracts \(565\)](#): NLT 20% of the Fluidextract portion taken remains as residue.
- [ARTICLES OF BOTANICAL ORIGIN, Total Ash\(561\)](#): NMT 3.0%
- [ARTICLES OF BOTANICAL ORIGIN, Acid-Insoluble Ash\(561\)](#): NMT 0.2%
- [pH \(791\)](#): 4.5–6.5
- **OTHER REQUIREMENTS:** Meets the requirements under [Botanical Extracts \(565\)](#), [General Pharmacopeial Requirements](#), sections for *Packaging and Storage*, *Labeling*, *Pesticide Residues*, and *Alcohol Content* for Fluidextracts

ADDITIONAL REQUIREMENTS

- [USP REFERENCE STANDARDS \(11\)](#).
[USP S-Allyl-L-cysteine RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
GARLIC FLUIDEXTRACT	Anton Bzhelyansky Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines

Chromatographic Database Information: [Chromatographic Database](#)