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Powdered Garcinia Hydroxycitrate Extract

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-notice-powdered-garcinia-hydroxycitrate-extract-20241122.

DEFINITION

Powdered Garcinia Hydroxycitrate Extract is prepared from *Garcinia cambogia* or *Garcinia indica* by extraction with water, alcohol, or mixtures of these solvents, followed by stabilization of the (–)-hydroxycitric acid content in the form of a calcium, potassium, magnesium, and/or sodium salt. The ratio of plant material to extract is about 5:1 to 10:1. It contains NLT 40% of (–)-hydroxycitric acid, calculated on the dried basis. It may contain suitable added substances.

IDENTIFICATION

• **A. HPLC IDENTIFICATION TEST:** The *Sample solution* chromatogram exhibits a peak for hydroxycitric acid at a retention time corresponding to that of *Standard solution A*, as obtained in the test for *Content of (–)-Hydroxycitric Acid and Limit of (–)-Hydroxycitric Acid Lactone*.

COMPOSITION

• CONTENT OF (–)-HYDROXYCITRIC ACID AND LIMIT OF (–)-HYDROXYCITRIC ACID LACTONE

Solution A: 30% phosphoric acid in water

Mobile phase: Dissolve 1.36 g of anhydrous potassium dihydrogen phosphate in 900 mL of water, adjust with *Solution A* to a pH of 2.5, complete to 1000 mL with water, mix, filter, and degas.

Solvent: A mixture of *Solution A* and water (1:9)

Standard solution A: A solution of [USP Calcium \(–\)-Hydroxycitrate RS](#) equivalent to about 2.5 mg/mL of (–)-hydroxycitric acid in *Solvent*. Before injection, pass through a membrane filter of 0.45-µm or finer pore size.

Standard solution B: 5 mg/mL of [USP Powdered Garcinia Hydroxycitrate Extract RS](#) in *Solvent*. Before injection, pass through a membrane filter of 0.45-µm or finer pore size.

Sample solution: 5 mg/mL of Powdered Garcinia Hydroxycitrate Extract in *Solvent*. Before injection, pass through a membrane filter of 0.45-µm or finer pore size.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; packing L1

Column temperature: 25 ± 1°

Flow rate: 1.0 mL/min

Injection size: 20 µL

System suitability

Samples: *Standard solution A* and *Standard solution B*

Suitability requirements

Chromatogram similarity: The chromatogram from *Standard solution B* is similar to the reference chromatogram provided with the lot of [USP Powdered Garcinia Hydroxycitrate Extract RS](#) being used.

Tailing factor: NMT 2.0 for the hydroxycitric acid peak, *Standard solution A*

Relative standard deviation: NMT 2.0%, determined from the hydroxycitric acid peak, *Standard solution A*

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*. [NOTE—*Standard solution A*, *Standard solution B*, and the *Sample solution* are stable for 6 h.]

Calculate the percentage of (–)-hydroxycitric acid and the limit of (–)-hydroxycitric acid lactone, if present, in the portion of Powdered Garcinia Hydroxycitrate Extract taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times F \times 100$$

r_U = peak area for the relevant analyte from the *Sample solution*

r_S = peak area of hydroxycitric acid from *Standard solution A*

C_s = concentration of (–)-hydroxycitric acid in *Standard solution A* (mg/mL)

C_u = concentration of Powdered Garcinia Hydroxycitrate Extract in the *Sample solution* (mg/mL)

F = conversion factor for each analyte: 2.17 for (–)-hydroxycitric acid lactone, and 1.00 for (–)-hydroxycitric acid

Acceptance criteria: NLT 40% of (–)-hydroxycitric acid and NMT 8% of (–)-hydroxycitric acid lactone on the dried basis

IMPURITIES

INORGANIC IMPURITIES

- **ARTICLES OF BOTANICAL ORIGIN, Acid-Insoluble Ash(561):** NMT 3.0%

ORGANIC IMPURITIES

- **PROCEDURE: BOTANICAL EXTRACTS (565), Preparations, General Pharmacopeial Requirements, Pesticide Residues:** Meets the requirements

SPECIFIC TESTS

• LIMIT OF CITRIC ACID

Solvent: Prepare as directed in the test for *Content of (–)-Hydroxycitric Acid and Limit of (–)-Hydroxycitric Acid Lactone*.

Standard solution: 0.5 mg/mL of [USP Citric Acid RS](#) in *Solvent*. Before injection, pass through a membrane filter of 0.45-µm or finer pore size.

Analysis

Sample: *Standard solution*

Calculate the percentage of citric acid in the portion of Powdered Garcinia Hydroxycitrate Extract taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times 100$$

r_u = peak area of citric acid, using the peak area of citric acid from the *Sample solution* in the test for *Content of (–)-Hydroxycitric Acid and Limit of (–)-Hydroxycitric Acid Lactone*

r_s = peak area of citric acid from the *Standard solution*

C_s = concentration of [USP Citric Acid RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Powdered Garcinia Hydroxycitrate Extract in the *Sample solution* in the test for *Content of (–)-Hydroxycitric Acid and Limit of (–)-Hydroxycitric Acid Lactone* (mg/mL)

Acceptance criteria: NMT 5% of citric acid on the dried basis

- **IDENTIFICATION TESTS—GENERAL (191):** Test for the presence of calcium, magnesium, potassium, and/or sodium.
- **LOSS ON DRYING (731):** Dry 2.0 g of Powdered Extract at 105° for 3 h: Powdered Extract containing calcium hydroxycitrate loses NMT 5.0% of its weight; Powdered Extract containing other salts loses NMT 9.0% of its weight.
- **MICROBIAL ENUMERATION TESTS (2021):** The total aerobic bacterial count does not exceed 10^4 cfu/g, and the total combined molds and yeasts count does not exceed 10^3 cfu/g.
- **MICROBIOLOGICAL PROCEDURES FOR ABSENCE OF SPECIFIED MICROORGANISMS (2022):** Meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.
- **OTHER REQUIREMENTS:** It meets the requirements of the test for *Residual Solvents* under [Botanical Extracts \(565\)](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, protected from light and moisture, and store at controlled room temperature.

Change to read:

- **LABELING:** The label states the Latin binomial and, following the official name, the part of the plant from which the article was prepared. It meets other *Labeling* requirements under [Botanical Extracts \(565\)](#). ▲ Dosage forms prepared with this article should bear the following statement: Do not use if you have a liver problem; discontinue use and consult a healthcare practitioner if you develop symptoms such as abdominal pain, dark urine, or jaundice (yellowing of the skin or eyes). ▲ (RB 1-Dec-2024)

- **USP REFERENCE STANDARDS (11).**

[USP Calcium \(–\)-Hydroxycitrate RS](#)

[USP Citric Acid RS](#)

[USP Powdered Garcinia Hydroxycitrate Extract RS](#)

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

Topic/Question	Contact	Expert Committee
POWDERED GARCINIA HYDROXYCITRATE EXTRACT	Anton Bzhelyansky Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines