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Ginkgo Capsules

DEFINITION

Ginkgo Capsules are prepared with Powdered Ginkgo Extract and contain, in the labeled amount of Powdered Ginkgo Extract, NLT 22.0% and NMT 27.0% of flavonol glycosides and NLT 5.4% and NMT 12.0% of terpene lactones, calculated as the sum of bilobalide ($C_{15}H_{18}O_8$), ginkgolide A ($C_{20}H_{24}O_9$), ginkgolide B ($C_{20}H_{24}O_{10}$), and ginkgolide C ($C_{20}H_{24}O_{11}$).

IDENTIFICATION

- **A. HPLC:** The retention times of the quercetin, isorhamnetin, and kaempferol peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the test for *Content of Flavonol Glycosides*. In the chromatogram of the *Sample solution*, the ratio of the kaempferol peak to the quercetin peak is NLT 0.7, and the isorhamnetin peak is NLT 0.1 times the size of the quercetin peak.
- **B. HPLC:** The retention times of the bilobalide, ginkgolide A, ginkgolide B, and ginkgolide C peaks of the *Sample solution* correspond to those of the *Standard solutions*, as obtained in the test for *Content of Terpene Lactones*.

STRENGTH

Change to read:

• CONTENT OF FLAVONOL GLYCOSIDES

Mobile phase: Methanol, water, and phosphoric acid (100:100:1)

▲ **Standard solution:** 0.2 mg/mL of [USP Quercetin RS](#), 0.2 mg/mL of [USP Kaempferol RS](#), and 0.05 mg/mL of [USP Isorhamnetin RS](#) in methanol ▲ (USP 1-Aug-2019)

Sample solution: Weigh and finely powder the contents of NLT 20 Capsules. Transfer an accurately weighed quantity of the powder, equivalent to about 50 mg of flavonol glycosides, to a 50-mL volumetric flask. Add 20 mL of methanol, and sonicate for 3 min. Add 20 mL of 1.5 N hydrochloric acid, and sonicate again for 10 min. Allow to cool to room temperature, and dilute with methanol to volume. Centrifuge, and transfer a portion of the clear supernatant to a rubber-capped, low-actinic glass vial. Heat in a steam bath for 25 min, and cool to room temperature in an ice bath.

Chromatographic system

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

Mode: LC

Detector: UV 370 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: ▲ *Standard solution* ▲ (USP 1-Aug-2019)

[NOTE—The relative retention times for quercetin, kaempferol, and isorhamnetin are about 1.0, 1.8, and 2.0, respectively. ▲ (USP 1-Aug-2019)]

Suitability requirements

Relative standard deviation: NMT 2.0% for quercetin ▲ (USP 1-Aug-2019)

Analysis

Samples: ▲ *Standard solution* ▲ (USP 1-Aug-2019) and *Sample solution*

Calculate the quantity, in mg, of each flavonol glycoside in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times C_S \times F \times 50$$

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

r_s = peak area of the relevant analyte from [▲]the *Standard solution* [▲](USP 1-Aug-2019)

C_s = concentration of the relevant analyte in [▲]the *Standard solution* [▲](USP 1-Aug-2019) (mg/mL)

F = mean molecular mass factor to convert each analyte into flavonol glycoside with a mean molecular mass of 756.7 (2.504 for quercetin, 2.437 for isorhamnetin, and 2.588 for kaempferol)

Calculate the total quantity, in mg, of flavonol glycosides in the portion of Capsules taken by adding the individual quantities calculated.

Calculate the total quantity, in mg/Capsule, of flavonol glycosides and the percentage of flavonol glycosides in the labeled amount of Powdered Ginkgo Extract.

Acceptance criteria: 22.0%–27.0% of flavonol glycosides

Change to read:

• **CONTENT OF TERPENE LACTONES**

[▲] (USP 1-Aug-2019)

Buffer solution: Dissolve 1.19 g of dibasic sodium phosphate and 8.25 g of monobasic potassium phosphate in 1000 mL of water, and adjust to a pH of 5.8.

Diluent: Methanol and water (1:1)

Solution A: Water

Solution B: Methanol

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	75	25
23	52	48
28	52	48
30	25	75
35	10	90
40	75	25
50	75	25

Standard solutions: Using the labeled content of the individual terpene lactones, prepare five solutions of the [USP Ginkgo Terpene Lactones RS](#) in *Diluent* within the range of 5–500 µg/mL for each of the relevant terpene lactones. Use sonication to dissolve the analytes if necessary. Pass through a filter of 0.45-µm or finer pore size.

Sample solution: Weigh and finely powder the contents of NLT 20 Capsules. Transfer an accurately weighed quantity of the powder, equivalent to about 120 mg of Powdered Ginkgo Extract, to a [▲]25-mL beaker. Add 10 mL of *Buffer solution*, and sonicate for 10 min. [▲] (USP 1-Aug-2019) Quantitatively transfer the solution to a glass chromatographic tube filled with chromatographic siliceous earth capable of holding 20 mL of aqueous phase.¹ Rinse the beaker with two 5-mL portions of *Buffer solution*, and transfer the washings to the column. [NOTE—Do not exceed 20 mL of total aqueous phase or the holding capacity of the chromatographic tube.] Allow the *Buffer solution* to be absorbed into the column. After 15 min, elute the column with 100 mL of ethyl acetate, collect the ethyl acetate solution, and evaporate to dryness under vacuum in a water bath maintained at 50°. Dissolve the residue in 20.0 mL of *Diluent*. [▲] Pass a portion of the solution through a filter of 0.45-µm or finer pore size and discard the first few milliliters of the filtrate. [▲] (USP 1-Aug-2019)

Chromatographic system

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

Mode: LC

Detector: Evaporative light-scattering. [NOTE—The parameters of the detector are adjusted to achieve the best signal-to-noise ratio according to manufacturer recommendations.]