

Ginkgo Tablets

Ginkgo Tablets are prepared from Powdered Ginkgo Extract and contain, in the labeled amount of Powdered Extract, not less than 22.0 percent and not more than 27.0 percent of flavonol glycosides and not less than 5.4 percent and not more than 12.0 percent of terpene lactones, consisting 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 ($C_{20}H_{24}O_{11}$).

Packaging and storage— Preserve in tight, light-resistant containers, and store at room temperature.

Labeling— The label states the Latin binomial and following the official name, the article used to prepare the Tablets. Label the Tablets to indicate the content, in mg, of Powdered Ginkgo Extract per Tablet.

Identification—

A: It meets the requirements of Identification test B under [Powdered Ginkgo Extract](#).

B: The retention times of the peaks for bilobalide, ginkgolide A, ginkgolide B, and ginkgolide C in the chromatogram of the Test solution correspond to those in the chromatogram of the Standard solutions, as obtained in the test for Content of terpene lactones.

[Disintegration and dissolution](#) [2040](#) : meet the requirements for Dissolution.

Medium: 0.1 N hydrochloric acid; 500 mL.

Apparatus 2: 75 rpm.

Time: 45 minutes.

Standard solutions— Proceed as directed in the test for Content of terpene lactones under Ginkgo.

Test solution— Combine 25-mL portions of the solution under test from each one of the six dissolution vessels in a separation funnel. Extract with four 50-mL portions of ethyl acetate.

Combine the extracts, and evaporate in vacuum to dryness. Dissolve the residue with sonication in 5.0 mL of a mixture of water and methanol (1:1).

Procedure— Proceed as directed in the test for Content of terpene lactones to determine the concentration, C, in mg per mL, of ginkgolide B in the Test solution. Calculate the percentage of ginkgolide B dissolved by the formula: $5000C/3G$

, in which C is as obtained above; and G is the content, in mg per Tablet, of ginkgolide B as determined in the test for Content of terpene lactones.

Tolerances— Not less than 75% of the content of ginkgolide B is dissolved in 45 minutes.

[Weight variation](#) [2091](#) : meet the requirements.

Content of flavonol glycosides—

Mobile phase— Proceed as directed in the test for Content of flavonol glycosides under Ginkgo.

Standard solutions— Proceed as directed for Standard solutions in the test for Content of flavonol glycosides under Ginkgo, except to obtain solutions having known concentrations of 0.2 mg per mL, 0.2 mg per mL, and 0.05 mg per mL, respectively.

Test solution— Weigh and finely powder not fewer than 20 Tablets. 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 about 3 minutes. Add 20 mL of 1.5 N hydrochloric acid, and sonicate again for about 10 minutes. Allow to cool to room temperature, dilute with methanol to volume, and mix. Centrifuge, and transfer a portion of the clear supernatant to a rubber-capped, low-actinic glass vial. Heat in a steam bath for 25 minutes, and cool to room temperature in an ice bath.

Chromatographic system— Prepare as directed in the test for Content of flavonol glycosides under [Ginkgo](#).

Procedure— Separately inject equal volumes (about 10 μ L) of each of the Standard solutions and the Test solution into the chromatograph, record the chromatograms, identify the peaks for quercetin, isorhamnetin, and kaempferol by comparison with the chromatogram obtained from the corresponding Standard solution, and measure the responses for those peaks. Separately calculate the quantities, in mg, of quercetin, isorhamnetin, and kaempferol glycosides in the portion of Tablets taken by the formula:

$$50(2.51)C(r_U / r_S)$$

in which 2.51 is the mean molecular mass factor to convert each analyte into a flavonol glycoside with a mean molecular mass of 756.7; C is the concentration, in mg per mL, of [USP Quercetin RS](#) in Standard solution 1; r_U is the peak response for the relevant analytes obtained from the Test solution; and r_S is the peak response of USP Quercetin RS in Standard solution 1. Calculate the

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

Content of terpene lactones—

Solvent, Buffer solution, Diluent, Solution A, Solution B, Mobile phase, Standard solutions, and

Chromatographic system— Proceed as directed in the test for Content of terpene lactones under [Ginkgo](#).

Test solution— Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed quantity of the powder, equivalent to about 120 mg of ginkgo extract, to a 30-mL glass centrifuge tube with a cap and PTFE gasket, and proceed as directed in the Test solution in the test for Content of terpene lactones under [Ginkgo](#), starting with “Add 10.0 mL of Solvent,” except to dissolve the final residue in 20.0 mL of Diluent.

Procedure— Proceed as directed for Content of terpene lactones under [Ginkgo](#). Separately calculate the quantities, in mg, 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 ($C_{20}H_{24}O_{11}$) in the portion of Tablets taken by the formula:

$$20C$$

in which C is as defined therein. Calculate the total quantity, in mg, of terpene lactones in the portion of Tablets taken by adding the individual quantities calculated.