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Terminalia chebula Fruit Dry Extract

DEFINITION

Terminalia chebula Fruit Dry Extract is prepared from the pericarp of the dried ripe fruits of *Terminalia chebula* Retz. (Fam. Combretaceae) by extraction with alcohol or water. It contains NLT 90% and NMT 110% of the labeled amount of hydrolyzable tannins, calculated as the sum of chebulagic acid and chebulinic acid on the dried basis.

IDENTIFICATION

Change to read:

- **A. HPTLC FOR ARTICLES OF BOTANICAL ORIGIN (203).**

Standard solution A: 0.1 mg/mL of [USP Chebulagic Acid RS](#) in methanol

Standard solution B: 100 mg/mL of [USP Terminalia chebula Fruit Dry Extract RS](#) in methanol. Sonicate for 10 min, centrifuge or filter, and use the supernatant or the filtrate.

Sample solution: Sonicate about 1 g of *Terminalia chebula* Fruit Dry Extract in 10 mL of methanol for 10 min, centrifuge or filter, and use the supernatant or the filtrate.

Chromatographic system

▲(See standard parameters as defined in [HPTLC for Articles of Botanical Origin \(203\), Table 1.](#))▲ (USP 1-Aug-2023)

Application volume: 5 µL of *Standard solution A* and 1 µL each of *Standard solution B* and *Sample solution*, as 8-mm bands

▲▲ (USP 1-Aug-2023)

Developing solvent system: Ethyl formate, toluene, formic acid, and water (30: 1.5: 4: 3)

▲▲ (USP 1-Aug-2023)

Derivatization reagent: Natural products reagent (NP reagent) prepared by dissolving 1 g of diphenylborinic acid aminoethylester in 200 mL of ethyl acetate

Analysis

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

Apply the *Samples* as bands and dry in air. Develop in a saturated chamber (20 min with filter paper), remove the plate from the chamber, and dry in air. Examine under ▲short-wave UV light.▲ (USP 1-Aug-2023) Heat the plate at 100° for 3 min, and then treat with the

Derivatization reagent. Examine under ▲long-wave UV light.▲ (USP 1-Aug-2023)

System suitability

Under ▲short-wave▲ (USP 1-Aug-2023) **UV light▲** (USP 1-Aug-2023) : Prior to derivatization, *Standard solution B* exhibits an intense band in the lower half of the chromatogram similar in R_f and color to the chebulagic acid band in *Standard solution A*. Another intense band above the chebulagic acid band is due to chebulinic acid. Two additional bands are observed above the chebulinic acid band, one near R_f 0.4 and another near R_f 0.7. Two additional bands are observed below the chebulagic acid band.

Under ▲long-wave▲ (USP 1-Aug-2023) **UV light▲** (USP 1-Aug-2023) : After derivatization, *Standard solution B* exhibits about six intense blue fluorescent bands and a pale blue band similar in R_f and color to the chebulagic acid band in *Standard solution A*.

Acceptance criteria

Under ▲short-wave▲ (USP 1-Aug-2023) **UV light▲** (USP 1-Aug-2023) : Prior to derivatization, the *Sample solution* exhibits two intense bands in the lower half of the chromatogram, with the lower band corresponding in R_f and color to the chebulagic acid band in *Standard solution A*. The following bands correspond to similar bands in *Standard solution B*: two bands below the chebulagic acid band, a band above chebulinic acid, and one intense band with an R_f of approximately 0.7.

Under ▲long-wave▲ (USP 1-Aug-2023) **UV light▲** (USP 1-Aug-2023) : After derivatization, the *Sample solution* exhibits about four intense blue fluorescent bands in the lower half of the chromatogram, and two blue fluorescent bands are observed between R_f 0.4 and 0.7. A

greenish-white band with an R_F near 0.5, characteristic of *Terminalia bellirica*, should not be observed.

• **B. HPLC**

Analysis: Proceed as directed in the test for *Content of Hydrolyzable Tannins*.

Acceptance criteria: The *Sample solution* exhibits peaks at retention times corresponding to those for chebulagic acid, ellagic acid, and chebulinic acid in *Standard solution B*. The most prominent peak corresponds to ellagic acid, followed in response by gallic acid with a retention time of approximately 6 min. Chebulagic acid is observed before ellagic acid and chebulinic acid is observed after ellagic acid, with almost equal responses.

COMPOSITION

Change to read:

• **CONTENT OF HYDROLYZABLE TANNINS**

Solution A: Dissolve 140 mg of potassium phosphate, monobasic in 900 mL of water, add 0.5 mL of o-phosphoric acid, dilute with water to 1 L, and mix.

Solution B: Acetonitrile

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
7	92	8
12	85	15
22	80	20
25	50	50
28	100	0
32	100	0

Standard solution A: 0.3 mg/mL of [USP Chebulagic Acid RS](#) in methanol

Standard solution B: Transfer 0.1 g of [USP Terminalia chebula Fruit Dry Extract RS](#) to a 100-mL volumetric flask and add 50 mL of boiling water. Sonicate and cool down to room temperature. Add water to make up the volume and mix well. Pass through a membrane filter of 0.45-µm or finer pore size.

Sample solution: Transfer 0.1 g of *Terminalia chebula* Fruit Dry Extract to a 100-mL volumetric flask. Add 70 mL of boiling water and sonicate for 10 min. Dilute with water to 100 mL, mix well, and pass through a membrane filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: ▲45°▲ (USP 1-Aug-2023)

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between the chebulagic acid peak and the following peak, *Standard solution B*

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

Relative standard deviation: NMT 2.0% for the chebulagic acid peak in repeated injections, *Standard solution A*

Chromatogram similarity: The chromatogram of *Standard solution B* is similar to the reference chromatogram provided with the lot of [USP Terminalia chebula Fruit Dry Extract RS](#) being used.