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Sour Jujube Seed Dry Extract

DEFINITION

Sour Jujube Seed Dry Extract is prepared from the sun-dried and ripened seeds of *Ziziphus jujuba* var. *spinosa* (Bunge) Hu ex H.F.Chow by extraction with water or hydroalcoholic mixtures. It contains NLT 90% and NMT 110% of the labeled amount of total triterpenoid glycosides calculated as the sum of jujuboside A ($C_{58}H_{94}O_{26}$) and jujuboside B ($C_{52}H_{84}O_{21}$) on the dried basis, and NLT 90% and NMT 110% of the labeled amount of total flavone C-glycosides calculated as the sum of spinosin ($C_{28}H_{32}O_{15}$) and 6"-feruloylspinosin ($C_{38}H_{40}O_{18}$) on the dried basis. It may contain suitable added substances as carriers.

IDENTIFICATION

Change to read:

- **A. HPTLC FOR ARTICLES OF BOTANICAL ORIGIN (203)**▲ (USP 1-Dec-2024)

Standard solution A: 0.5 mg/mL of [USP Spinosin RS](#)▲ and 1 mg/mL of [USP Jujuboside A RS](#)▲ (USP 1-Dec-2024) in [methanol](#). Sonicate to dissolve.

Standard solution B:▲ Add 0.5▲ (USP 1-Dec-2024) g of [USP Ziziphus jujuba spinosa Seed Dry Extract RS](#) into 2 mL of [methanol](#). Sonicate for 30 min, centrifuge for 5 min, and use the supernatant.

Sample solution:▲ Add 0.5▲ (USP 1-Dec-2024) g (adjust the amount, if necessary) of Sour Jujube Seed Dry Extract into▲ 2▲ (USP 1-Dec-2024) mL of [methanol](#). Sonicate for 30 min,▲ centrifuge for 5 min,▲ (USP 1-Dec-2024) and use the supernatant.

Chromatographic system

▲ (See standard parameters as defined in [HPTLC for Articles of Botanical Origin \(203\)](#), [Table 1.](#))▲ (USP 1-Dec-2024)

Application volume: 5 µL

▲▲ (USP 1-Dec-2024)

Developing solvent system:▲ [Dichloromethane](#), [glacial acetic acid](#), [methanol](#), and [water](#) (16:8:3:2)▲ (USP 1-Dec-2024)

Derivatization reagent A:▲ 5▲ (USP 1-Dec-2024) mg/mL of [2-aminoethyl diphenylborinate](#) in▲ [ethyl alcohol](#)▲ (USP 1-Dec-2024)

Derivatization reagent B: 50 mg/mL of [polyethylene glycol 400](#) in▲ [ethyl alcohol](#)

Derivatization reagent C: Prepare an anisaldehyde–sulfuric acid reagent as follows. Mix 85 mL of ice-cooled [methanol](#) with 10 mL of [glacial acetic acid](#), 5 mL of sulfuric acid, and 0.5 mL of [p-anisaldehyde](#).▲ (USP 1-Dec-2024)

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, remove the plate from the chamber, and dry the plate at 100° for 3 min. Treat the plate with *Derivatization reagent A* and dry for 5 min with a stream of cool air. Immediately treat the plate with *Derivatization reagent B*, dry for 5 min with a stream of cool air, and examine under long-wave UV light.▲ Then treat the plate with *Derivatization reagent C*, heat at 100° for 3 min, and examine under white light.▲ (USP 1-Dec-2024)

System suitability

▲ **Under long-wave UV light:**▲ (USP 1-Dec-2024) *Standard solution A* exhibits a▲ greenish-▲ (USP 1-Dec-2024) yellow band due to spinosin in the middle-third section. *Standard solution B* exhibits a band corresponding in R_f and color to spinosin in *Standard solution A*, a▲ brownish-▲ (USP 1-Dec-2024) yellow band below spinosin, a weak yellow band above▲ or partially overlapped with▲ (USP 1-Dec-2024) spinosin, a▲ bluish-green▲ (USP 1-Dec-2024) band due to 6"-feruloylspinosin above the weak yellow band,▲ a blue band due to magnoflorine above the 6"-feruloylspinosin band, up to three faint bluish-green bands above the blue band, and a weak blue band above the faint bluish-green band.

Under white light: After treating the plate with *Derivatization reagent C*, *Standard solution A* exhibits a brown band due to jujuboside A in the lower-third section and a yellow band due to spinosin in the middle-third section. *Standard solution B* exhibits, in the lower-third section, a band corresponding in R_f to jujuboside A in *Standard solution A*, three olive green bands below jujuboside A, and a weak olive green band above jujuboside A; in the middle-third section, a weak brown band due to jujuboside B, a faint band immediately below jujuboside B located at an R_f corresponding to spinosin, and a faint band above jujuboside B; and in the upper-third section, a pair of violet bands and a violet band above the pair of bands.▲ (USP 1-Dec-2024)

Acceptance criteria

▲**Under long-wave UV light:**▲ (USP 1-Dec-2024) The *Sample solution* exhibits the following bands corresponding to similar bands in *Standard solution B*: ▲a greenish-▲ (USP 1-Dec-2024) yellow band ▲in the middle-third section▲ (USP 1-Dec-2024) corresponding in R_f to spinosin in *Standard solution A*, a ▲brownish-▲ (USP 1-Dec-2024) yellow band below spinosin, a weak yellow band above ▲or partially overlapped with▲ (USP 1-Dec-2024) spinosin, a ▲bluish-green▲ (USP 1-Dec-2024) band due to 6"-feruloylspinosin above the weak yellow band, ▲a blue band due to magnoflorine (a distinction from the seeds of *Hovenia dulcis* and *Cercis chinensis*) above 6"-feruloylspinosin, up to three faint bluish-green bands above the blue band, and a weak blue band above the faint bluish-green bands.

Under white light: After treating the plate with *Derivatization reagent C*, the *Sample solution* exhibits the following bands corresponding to similar bands in *Standard solution B*: in the lower-third section, a band corresponding in R_f to jujuboside A in *Standard solution A*, three olive green bands below jujuboside A, and a weak olive green band above jujuboside A; in the middle-third section, a weak brown band due to jujuboside B, a faint band immediately below jujuboside B located at an R_f corresponding to spinosin, and a faint band above jujuboside B; and in the upper-third section, a pair of violet bands and a violet band above the pair of bands. Purplish-black bands are observed close to the solvent front.▲ (USP 1-Dec-2024)

Delete the following:

▲• B. [HPTLC FOR ARTICLES OF BOTANICAL ORIGIN \(203\)](#).▲ (USP 1-Dec-2024)

Change to read:

• ▲B.▲ (USP 1-Dec-2024) **HPLC**

Analysis: Proceed as directed in the test for *Content of Triterpenoid Glycosides*.

Acceptance criteria: The *Sample solution* exhibits a peak at the retention time corresponding to jujuboside A (a distinction from the seeds of *Ziziphus mauritiana*, *H. dulcis*, and *C. chinensis*) in *Standard solution 6*, two small triterpenoid glycoside peaks due to jujuboside A1 and jujuboside B, three flavonoid peaks, and a peak due to magnoflorine with its isomer at the retention times corresponding to the same constituents in *Standard solution 7*. The jujuboside A1 peak has less intensity than the jujuboside B peak. The first flavonoid peak is a co-elution of spinosin and an unidentified constituent; the second flavonoid peak is a co-elution of 6"-feruloylspinosin and an unidentified constituent; the third flavonoid peak is an unidentified flavonoid. The first flavonoid peak is more intense than the second, which is more intense than the third. Besides the above-mentioned peaks, no peak between jujuboside A and jujuboside B is more intense than the peak corresponding to jujuboside A1.

COMPOSITION

Change to read:

• **CONTENT OF TRITERPENOID GLYCOSIDES**

[NOTE—Proceed under low-actinic light. The *Standard solutions* and the *Sample solution* are stable for 24 h at room temperature.]

Solution A: [Water](#)

Solution B: [Acetonitrile](#)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
15	60	40
23	60	40