Schisandra chinensis Fruit

Final Authorized Version 1.0

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**DEFINITION**
The article consists of the dried ripe fruits of *Schisandra chinensis* (Turcz.) Baill. (Family Schisandraceae) collected in the fall. It contains NLT 0.40% of schisandrin (schisandrol A, C\(_{24}\)H\(_{32}\)O\(_7\)) on the dried basis; and NLT 0.95% of total lignans calculated as the sum of schisandrin, schisandrol B (C\(_{23}\)H\(_{28}\)O\(_7\)), schisandrin A (deoxyschisandrin, C\(_{24}\)H\(_{32}\)O\(_6\)), and schisandrin B (γ-schisandrin, C\(_{23}\)H\(_{28}\)O\(_6\)), on the dried basis.

**SYNONYMS**
*Kadsura chinensis* Turcz.
*Maximowiczia amurensis* Rupr.
*Maximowiczia chinensis* (Turcz.) Rupr.
*Maximowiczia japonica* (A.Gray) K. Koch
*Maximowiczia sinensis* Rob.
*Sphaerostema japonicum* A.Gray

**POTENTIAL CONFOUNDING MATERIALS**
*Kadsura japonica* (L.) Dunal
*Schisandra sphenanthera* Rehder & E. H. Wilson

**SELECTED COMMON NAMES**
**Chinese:** 五味子 (Wu Wei Zi), 北五味子 (Bei Wu Wei Zi)
**English:** Schisandra, Northern schisandra, Chinese magnolia vine, five flavor fruit, magnolia vine
**Finnish:** Palsamiköynnös
**French:** Schisandra de Chine
**German:** Chinesisches Spaltkölbchen, Chinesischer Limonenbaum
**Japanese:** ゴミシ
**Korean:** 오미자
**Russian:** Лимонник китайский
**Swedish:** Fjärilsranka

**CONSTITUENTS OF INTEREST**
**Lignans:** Schisandrin (schisandrol A), schisandrol B, schisandrin A (deoxyschisandrin), and schisandrin B (γ-schisandrin)

**IDENTIFICATION**
• A. BOTANICAL CHARACTERISTICS

Macroscopic: Irregularly spheroidal or compressed-spheroidal, 5–8 mm in diameter; externally red, purplish-red, or dull red, shrunk, oily, sometimes blackish-red, or covered with “white frost”; pulp soft, containing one or two reniform seeds; seeds externally brownish-yellow, shiny; testa thin and fragile.

Microscopic

Transverse section: Exocarp consists of one layer of epidermal cells, oil cells presented scattered; mesocarp consists of 10 or more layers of parenchymatous cells containing starch granules, small collateral vascular bundles presented scattered; endocarp consists of one layer of square parenchymatous cells. Outmost layer of testa consists of radially elongated stone cells with thickened walls, fine and dense pits and pit canals; beneath showing several layers of stone cells, sub-rounded, triangular, or polygonal with larger pits; a few layers of parenchymatous cells occur underneath the stone cell layers; raphe has vascular bundles; oil cell layer consists of one layer of rectangular oil cells containing yellowish-brown oil, with 3–5 layers of small cells lying below. Inner layer of testa consists of small cells with slightly thickened walls; endosperm cells containing oil droplets and aleurone grains.

• B. THIN-LAYER CHROMATOGRAPHY

Standard solution A: 0.5 mg/mL of USP Schisandrin RS in methanol

Standard solution B: Sonicate 100 mg/mL of USP Schisandra chinensis Fruit Dry Extract RS in methanol for 10 min. Centrifuge and use the supernatant.

Sample solution: Sonicate 2.5 g of Schisandra chinensis Fruit, finely powdered, in 10 mL of methanol for 10 min. Centrifuge and use the supernatant.

Chromatographic system

(See Chromatography <621>, [1] Thin-Layer Chromatography.)

Adsorbent: Chromatographic silica gel F254 mixture with an average particle size of 5 µm (HPTLC plates)

Application volume: 3 µL, as 8-mm bands

Relative humidity: Condition the plate to a relative humidity of about 33% using a suitable device.

Developing solvent system: Toluene, ethyl acetate, and glacial acetic acid (23:6:1)

Developing distance: 6 cm

Derivatization reagent: 10% Sulfuric acid in ethanol. [Note—Slowly add sulfuric acid to ice-cold ethanol.]

Analysis

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

Apply the Samples as bands to a suitable HPTLC plate and dry in air. Develop the chromatograms in a saturated chamber, remove the plate from the chamber, air-dry, and examine under UV light at 254 nm. Then treat the plate with Derivatization reagent, heat at 120° for 7 min, and examine under UV light at 366 nm.

System suitability: Under UV light at 254 nm, Standard solution B exhibits an intense band corresponding in Rf to the band of schisandrin in Standard solution A. Standard solution B also exhibits a band due to schisandrin A in the middle, and four or five bands between the positions of the bands of schisandrin and schisandrin A. In the upper-half, Standard solution B exhibits a band corresponding to schisandrin B.

Acceptance criteria: Under UV light at 254 nm, the Sample solution exhibits an intense band corresponding in Rf to the band due to schisandrin (distinction from Schisandra sphenanthera Fruit) in Standard solution A. The Sample solution exhibits additional bands including one or two bands below the position of schisandrin; a band due to schisandrin A in the middle; four or five bands between the positions of the bands of schisandrin A and schisandrin; and two or three bands in the upper-half, the
most intense band is at an \( R_f \) corresponding to the band of schisandrin B in Standard solution B. Under UV light at 366 nm after derivatization, the Sample solution does not exhibit an intense blue fluorescent band (distinction from Schisandra sphenanthera Fruit) in the upper-third.

**C. HPLC**

**Analysis:** Proceed as directed in the Assay for Content of Lignans.

**Acceptance criteria:** The chromatogram of the Sample solution exhibits the most intense peak with a retention time corresponding to schisandrin in Standard solution A, and peaks for schisandrol B, schisandrin A, and schisandrin B corresponding to the retention times for the same lignans in Standard solution B. There is no principal peak due to schisantherin A at a relative retention time of about 2.1 relative to schisandrin (distinction from Schisandra sphenanthera Fruit).

**ASSAY**

**CONTENT OF LIGNANS**

**Solution A:** Water

**Solution B:** Acetonitrile and methanol (1:1)

**Mobile phase:** See Table 1.

### Table 1

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>Solution A (%)</th>
<th>Solution B (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>47</td>
<td>53</td>
</tr>
<tr>
<td>30</td>
<td>20</td>
<td>80</td>
</tr>
</tbody>
</table>

**Standard solution A:** 0.06 mg/mL of USP Schisandrin RS in methanol

**Standard solution B:** 10 mg/mL of USP Schisandra chinensis Fruit Dry Extract RS in methanol. Sonicate and pass through a polytetrafluoroethylene filter of 0.2-μm pore size before injection.

**Sample solution:** Accurately transfer about 250 mg of Schisandra chinensis Fruit, finely powdered, into a 50-mL centrifuge tube. Add 10 mL of methanol and sonicate for 10 min (140 W, 42 kHz). Centrifuge and transfer the supernatant to a 25-mL volumetric flask. Repeat the extraction one more time. Combine the extracts in the 25-mL volumetric flask and dilute with methanol to volume. Mix, pass through a polytetrafluoroethylene filter of 0.2-μm pore size before injection, and discard the first portion of the filtrate.

**Chromatographic system**

(See Chromatography <621>, System Suitability.)

**Mode:** UPLC

**Detector:** UV 251 nm

**Column:** 2.1 mm × 15 cm; 1.8-μm packing L1 (similar to ACQUITY UPLC® HSS T3)

**Column temperature:** 35º

**Flow rate:** 0.3 mL/min

**Injection volume:** 3 μL

**System suitability**

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

**Suitability requirements**

**Chromatogram similarity:** The chromatogram of Standard solution B is similar to the reference chromatogram provided with the lot of USP Schisandra chinensis Fruit Dry Extract RS being used.
**Resolution:** NLT 1.5 between the schisandrol B peak and the peak following it, *Standard solution B*

**Tailing factor:** NMT 2.0 for schisandrin peak, *Standard solution A*

**Relative standard deviation:** NMT 2.0% for the schisandrin peak, *Standard solution A*

**Analysis**

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

Using the chromatograms of *Standard solution A, Standard solution B,* and the reference chromatogram provided with the lot of USP *Schisandra chinensis* Fruit Dry Extract RS being used, identify the peaks corresponding to schisandrin, schisandrol B, schisandrin A, and schisandrin B in the *Sample solution.* [Note—The approximate relative retention times of the analytes are provided in Table 2.]

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Approximate Relative Retention Time</th>
<th>Conversion Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schisandrin</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Schisandrol B</td>
<td>1.29</td>
<td>1.21</td>
</tr>
<tr>
<td>Schisandrin A</td>
<td>2.90</td>
<td>1.00</td>
</tr>
<tr>
<td>Schisandrin B</td>
<td>3.31</td>
<td>1.23</td>
</tr>
</tbody>
</table>

Separately calculate the percentages of schisandrin, schisandrol B, schisandrin A, and schisandrin B in the portion of *Schisandra chinensis* Fruit taken:

\[
\text{Result} = \left( \frac{r_u}{r_s} \right) \times C_s \times \left( \frac{V}{W} \right) \times F \times 100
\]

- \( r_u \) = peak area of the relevant analyte from the *Sample solution*
- \( r_s \) = peak area of schisandrin from *Standard solution A*
- \( C_s \) = concentration of USP Schisandrin RS in *Standard solution A* (mg/mL)
- \( V \) = volume of the *Sample solution* (mL)
- \( W \) = weight of *Schisandra chinensis* Fruit taken to prepare the *Sample solution* (mg)
- \( F \) = conversion factors for analytes (see Table 2)

Calculate the percentage of total lignans as the sum of schisandrin, schisandrol B, schisandrin A, and schisandrin B.

**Acceptance criteria**

- **Schisandrin:** NLT 0.40% on the dried basis
- **Total lignans:** NLT 0.95% on the dried basis

**CONTAMINANTS**

- **Articles of Botanical Origin** [2], *General Method for Pesticide Residues Analysis <561>*: [2] [3] Meets the requirements

- **Elemental Impurities—Procedures <233>* [3]

**Acceptance criteria**

- **Arsenic:** NMT 2.0 μg/g
- **Cadmium:** NMT 0.3 μg/g
- **Lead:** NMT 5.0 μg/g
Mercury: NMT 0.2 μg/g

• **Microbial Enumeration Tests <61>:** [4] The total aerobic bacterial count does not exceed $10^5$ cfu/g, the total combined molds and yeasts count does not exceed $10^3$ cfu/g, and the bile-tolerant Gram-negative bacteria does not exceed $10^1$ cfu/g.

• **Tests for Specified Microorganisms <62>:** [5] Meets the requirements of the tests for the absence of *Salmonella* species and *Escherichia coli*


**Specific Tests**

• **Articles of Botanical Origin [2], Foreign Organic Matter <561>:** [2] NMT 1.0%

• **Loss on Drying <731>:** [7]
  Sample: 2.0 g of *Schisandra chinensis* Fruit, moderately powdered
  Analysis: Dry the Sample at 105° for 5 h.
  Acceptance criteria: NMT 16.0%

• **Articles of Botanical Origin [2], Total Ash <561>:** [2]
  Analysis: 2.0 g of *Schisandra chinensis* Fruit, moderately powdered
  Acceptance criteria: NMT 7.0%

• **Articles of Botanical Origin [2], Water-Soluble Extractives <561>:** [2]
  Analysis: Cold extraction method
  Acceptance criteria: NLT 35%

• **Articles of Botanical Origin [2], Total Alcohol-Soluble Extractives <561>:** [2]
  Analysis: Cold extraction method
  Acceptance criteria: NLT 40%

**Additional Requirements**

• **Packaging and Storage:** Preserve in well-closed containers, protected from light and moisture, and store at controlled room temperature.

• **Labeling:** The label states the Latin binomial and the part(s) of the plant contained in the article.

• **USP Reference Standards <11>:** [8]
  USP Aflatoxins RS [6]
  USP *Schisandra chinensis* Fruit Dry Extract RS
  USP Schisandrin RS

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