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Pummelo Peel Flavonoids Dry Extract

Change to read:

DEFINITION

Pummelo Peel Flavonoids Dry Extract, also known as Pomelo Peel Flavonoids Dry Extract, is ▲prepared▲ (USP 1-Dec-2023) from the dried exocarp and mesocarp of the unripe fruit of *Citrus maxima* (Burm.) Merr. [syn. *Citrus grandis* (L.) Osbeck] by extraction with water, precipitation with ethanol, and concentration of the filtrate under reduced pressure followed by standing to allow the precipitate to settle, after which the precipitate is collected and dried at below 60°. It contains NLT 60% of total flavonoid glycosides, calculated as the sum of naringin ($C_{27}H_{32}O_{14}$) and rhoifolin ($C_{27}H_{30}O_{14}$) on the dried basis. It may contain suitable added substances as carriers.

IDENTIFICATION

Change to read:

• A. HPTLC FOR ARTICLES OF BOTANICAL ORIGIN (203).

Standard solution A: 1.0 mg/mL of [USP Naringin RS](#) in [methanol](#). Sonicate to dissolve.

Standard solution B: 10 mg/mL of [USP Citrus maxima Peel Flavonoids Dry Extract RS](#) in [methanol](#). Sonicate for 15 min, centrifuge, and use the supernatant.

Sample solution: 10 mg/mL of Pummelo Peel Flavonoids Dry Extract in [methanol](#). Sonicate for 15 min, centrifuge, and use the supernatant.

Chromatographic system

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

Application volume: 2 µL

▲▲ (USP 1-Dec-2023)

Developing solvent system: [Ethyl acetate](#), [formic acid](#), and [water](#) (100:15:13)

Derivatization reagent A: 10 mg/mL of [2-aminoethyl diphenylborinate](#) in [methanol](#)

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

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 in a current of cool air. Immediately treat the plate with

Derivatization reagent B, dry for 5 min in a current of cool air, and examine under ▲long-wave UV light.▲ (USP 1-Dec-2023)

System suitability: *Standard solution A* exhibits a yellowish-brown band due to naringin in the lower-half section. *Standard solution B* exhibits a band corresponding in R_f and color to the band due to naringin in *Standard solution A*, a blue band above naringin, and a bright blue band stained with yellow due to rhoifolin immediately below naringin. In the upper-half section, *Standard solution B* exhibits a green band close to the solvent front, three blue bands below the green band with the bottom blue band due to meranzin hydrate, and a weak yellowish-brown band below meranzin hydrate.

Acceptance criteria: The *Sample solution* exhibits the following bands corresponding in R_f to the same bands in *Standard solution B*: in the lower-half section, a yellowish-brown band corresponding in R_f and color to the band due to naringin in *Standard solution A*, a blue band above naringin, and a bright blue band due to rhoifolin stained with yellow possibly immediately below naringin; in the upper-half section, a green band close to the solvent front, three blue bands below the green band with the bottom blue band due to meranzin hydrate (a distinction from *Citrus reticulata* peel), and a weak yellowish-brown band below meranzin hydrate. In addition, some minor bands may be visible.

• B. HPLC

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

Acceptance criteria: *Standard solution A* exhibits three peaks due to naringin, hesperidin, and rhoifolin with increasing retention times. The

Sample solution exhibits the most intense peak and a small peak at retention times corresponding to naringin and rhoifolin, respectively.

Standard solution A, and a small peak due to meranzin hydrate, which is a coumarin, at a relative retention time of about 2.3 relative to naringin. The *Sample solution* does not exhibit a principal peak at a retention time corresponding to hesperidin in *Standard solution A* (a distinction from *C. reticulata* peel). Any other peak between naringin and rhoifolin and between rhoifolin and meranzin hydrate is not more intense than or similar to the peak of rhoifolin. The content ratio of naringin to rhoifolin is more than 50.

COMPOSITION

Change to read:

• CONTENT OF FLAVONOID GLYCOSIDES

Solution A: ▲0.6%▲ (USP 1-Dec-2023) [glacial acetic acid](#) in [water](#)

Solution B: [Methanol](#)

Mobile phase: ▲See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	66	34
20	62	38
21	5	95
27	5	95
28	66	34
35	66	34▲ (USP 1-Dec-2023)

Solvent: [Methanol](#) and [water](#) (7:3)

Rhoifolin solution: 0.10 mg/mL of [USP Rhoifolin RS](#) in *Solvent*

Standard solution A: Accurately transfer about 2.5 mg of [USP Naringin RS](#) and 1.0 mg of [USP Hesperidin RS](#) to a 5-mL volumetric flask, add 2 mL of [methanol](#), and sonicate for 10 min. Cool to room temperature, accurately add 2.5 mL of *Rhoifolin solution* to the volumetric flask, dilute with *Solvent* to volume, and mix well.

Standard solution B: 0.5 mg/mL of [USP Citrus maxima Peel Flavonoids Dry Extract RS](#) in *Solvent*. Sonicate for 15 min, centrifuge, and pass through a suitable membrane filter of 0.45-µm or finer pore size.

Sample solution: Accurately transfer about 5.0 mg of Pummelo Peel Flavonoids Dry Extract to a 10-mL volumetric flask, add 5 mL of [methanol](#), and sonicate for 15 min. Cool to room temperature, add 50% [methanol](#) to volume, and mix well. Before injection, pass through a suitable membrane filter of 0.45-µm or finer pore size, and discard the first portion of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 320 nm

Column: 4.6-mm × 15-cm; ▲3.5-µm▲ (USP 1-Dec-2023) packing [L1](#)

Column temperature: 35°

Flow rate: ▲1.3▲ (USP 1-Dec-2023) mL/min

Injection volume: 10 µL

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between the naringin and hesperidin peaks, *Standard solution A*

Tailing factor: NMT 2.0 for the naringin and rhoifolin peaks, *Standard solution A*

Relative standard deviation: NMT 2.0% for the naringin and rhoifolin peaks 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 Citrus maxima Peel Flavonoids Dry Extract RS](#) being used.

Analysis