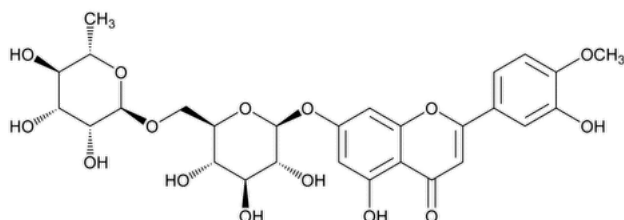


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Diosmin



$C_{28}H_{32}O_{15}$ 608.54

5-Hydroxy-2-(3-hydroxy-4-methoxyphenyl)-7-[(2S,3R,4S,5S,6R)-3,4,5-trihydroxy-6-[[[(2R,3R,4R,5R,6S)-3,4,5-trihydroxy-6-methyloxan-2-yl]oxymethyl]oxan-2-yl]oxy]chromen-4-one;

7-[[[6-O-(6-Deoxy- α -L-mannopyranosyl)- β -D-glucopyranosyl]oxy]-5-hydroxy-2-(3-hydroxy-4-methoxyphenyl)-4H-1-benzopyran-4-one CAS RN®: 520-27-4.

DEFINITION

Diosmin contains NLT 90.0% and NMT 102.0% of diosmin ($C_{28}H_{32}O_{15}$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Mobile phase: Methanol, acetonitrile, acetic acid, and water (27:2:6:65)

Standard solution: 1.0 mg/mL of [USP Diosmin RS](#) in dimethyl sulfoxide

System suitability solution: 1 mg/mL of [USP Diosmin for System Suitability RS](#) in dimethyl sulfoxide

Sample solution: 1.0 mg/mL of Diosmin in dimethyl sulfoxide

Chromatographic system

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

Mode: LC

Detector: UV 275 nm

Column: 4.6-mm $\times$ 10-cm; 3- μ m packing L1

Column temperature: 40°

Flow rate: 1.2 mL/min

Injection size: 10 μ L

System suitability

Samples: *System suitability solution* and *Standard solution*.

[NOTE—Allow the run time about 6 times the diosmin retention time. The relative retention times for diosmin, acetoisovanillone, hesperidin, isorhoifolin, linarin, and diosmetin are 1, 0.5, 0.6, 0.8, 2.6, and 4.5, respectively.]

Suitability requirements

Chromatogram similarity: The chromatogram from the *System suitability solution* is similar to the Reference Chromatogram provided with the [USP Diosmin for System Suitability RS](#) being used.

Resolution: NLT 2.5 between hesperidin and isorhoifolin, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of diosmin ($C_{28}H_{32}O_{15}$), in the portion of Diosmin taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Diosmin RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Diosmin in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–102.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#)

Sample: 1.0 g

Acceptance criteria: NMT 0.2%

• LIMIT OF IODINE

Determine the total content of iodine by potentiometry, using an iodide-selective electrode, after oxygen flask combustion (see [Oxygen Flask Combustion \(471\)](#)).

Sample solution: [CAUTION—Observe rigorously the precautions set forth for *Procedure* under [Oxygen Flask Combustion \(471\)](#).]

Wrap 0.100 g of Diosmin in a piece of free-halide filter paper, and place it in the platinum gauze specimen holder. Introduce into the flask 50.0 mL of a 0.2 g/L solution of hydrazine. Flush the flask with oxygen for 10 min. Ignite the filter paper. Stir the contents of the flask immediately after the end of the combustion to dissolve completely the combustion products. Continue stirring for 1 h.

Standard solution: 33.2 µg/mL of potassium iodide in water, equivalent to 25.4 µg/mL of iodine

Potassium nitrate solution: 200 mg/mL of potassium nitrate in 0.1 M nitric acid

Analysis

Samples: *Sample solution* and *Standard solution*

Transfer 30 mL of *Potassium nitrate solution* to a beaker, immerse the electrodes, and stir for 10 min. The potential (nU_1) must remain stable. Measure the potential (nU_1). Add 1 mL of the *Sample solution*, and measure the potential (nU_2).

Transfer 30 mL of *Potassium nitrate solution* to a beaker, immerse the electrodes, and stir for 10 min. The potential (nS_1) must remain stable. Measure the potential (nS_1). Add 80 µL of the *Standard solution*, and measure the potential (nS_2).

Acceptance criteria: NMT 0.1%: The absolute value $|nU_2| - |nU_1|$ is not higher than the absolute value $|nS_2| - |nS_1|$.

• RELATED COMPOUNDS

Mobile phase, System suitability solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: 0.05 mg/mL of [USP Diosmin RS](#) in dimethyl sulfoxide

System suitability

Sample: *System suitability solution*. [NOTE—Allow the run time about 6 times that of the diosmin retention time. The relative retention times for diosmin, acetoisovanillone, hesperidin, isorhoifolin, linarin, and diosmetin are 1, 0.5, 0.6, 0.8, 2.6, and 4.5, respectively.]

System suitability requirements

Chromatogram similarity: The chromatogram from the *System suitability solution* is similar to the Reference Chromatogram provided with the [USP Diosmin for System Suitability RS](#) being used.

Resolution: NLT 2.5 between hesperidin and isorhoifolin, *System suitability solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Diosmin taken: [NOTE—Disregard any impurity less than 0.1%.]

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times F \times 100$$

r_U = peak response for each impurity from the *Sample solution*

r_S = peak response for diosmin from the *Standard solution*

C_S = concentration of [USP Diosmin RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Diosmin in the *Sample solution* (mg/mL)

F = correction factor for each individual impurity (see [Table 1](#))

Acceptance criteria

Total impurities: NMT 10%

Individual impurities: See [Table 1](#).

Total other impurities and acetoisovanillone: NMT 1%

Table 1