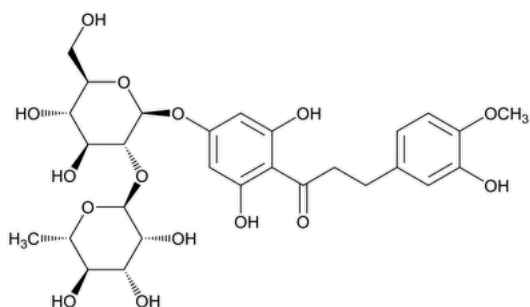


Status: Currently Official on 15-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: NF Monographs
 DocId: GUID-0ABA58A9-C8AD-4B69-BBEA-F9CD228BD501_3_en-US
 DOI: https://doi.org/10.31003/USPNF_M6123_03_01
 DOI Ref: dn6ss

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Add the following:

▲Neohesperidin Dihydrochalcone



$C_{28}H_{36}O_{15}$ 612.58

1-Propanone, 1-[4-[[2-O-(6-deoxy-α-L-mannopyranosyl)-β-D-glucopyranosyl]oxy]-2, 6-dihydroxyphenyl]-3-(3-hydroxy-4-methoxyphenyl)-; 3,5-Dihydroxy-4-[3-(3-hydroxy-4-methoxyphenyl)propanoyl]phenyl 2-O-(α-L-rhamnopyranosyl)-β-D-glucopyranoside CAS RN®: 20702-77-6.

DEFINITION

Neohesperidin Dihydrochalcone contains NLT 96.0% and NMT 102.0% of neohesperidin dihydrochalcone ($C_{28}H_{36}O_{15}$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- A. ▲ **SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: **197A**▲ (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

Solution A: 0.5% (v/v) [glacial acetic acid](#) in water

Mobile phase: [Acetonitrile](#) and *Solution A* (20:80)

Diluent: [Dimethyl sulfoxide](#)

System suitability solution: Suspend 100 mg of [USP Neohesperidin Dihydrochalcone RS](#) in 10.0 mL of a 100-g/L solution of [sulfuric acid](#) in water. Heat the suspension for 5 min on a boiling water bath. Immediately dilute 1.0 mL of the resulting solution with *Diluent* to 50.0 mL.

[NOTE—Neohesperidin dihydrochalcone related compound F and neohesperidin dihydrochalcone related compound G are prepared in situ in this solution.]

Standard solution: 1.0 mg/mL of [USP Neohesperidin Dihydrochalcone RS](#) in *Diluent*

Sample solution: 1.0 mg/mL of Neohesperidin Dihydrochalcone in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 282 nm

Column: 3.9-mm × 15-cm; 4-μm packing [L1](#), with a carbon loading of 7%

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 10 μL

Run time: 5 times the retention time of neohesperidin dihydrochalcone

System suitability

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

[NOTE—For the approximate relative retention times of related substances, see [Table 1](#).]

Suitability requirements

Resolution: NLT 2.5 between the neohesperidin dihydrochalcone peak and the neohesperidin dihydrochalcone related compound F peak, *System suitability solution*

Relative standard deviation: NMT 2.0%, determined from the neohesperidin dihydrochalcone peak, *Standard solution*

Chromatogram similarity: The chromatogram obtained from the *Standard solution* is similar to the reference chromatogram provided with the lot of [USP Neohesperidin Dihydrochalcone RS](#) being used.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of neohesperidin dihydrochalcone ($C_{28}H_{36}O_{15}$) in the portion of Neohesperidin Dihydrochalcone taken:

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

r_U = peak area of neohesperidin dihydrochalcone from the *Sample solution*

r_S = peak area of neohesperidin dihydrochalcone from the *Standard solution*

C_S = concentration of [USP Neohesperidin Dihydrochalcone RS](#) in the *Standard solution*

C_U = concentration of Neohesperidin Dihydrochalcone in the *Sample solution*

Acceptance criteria: 96.0%–102.0% on the anhydrous basis

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.2%

• **ORGANIC IMPURITIES**

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

Standard solution A: Use the *Standard solution*, as prepared in the Assay.

Standard solution B: 0.04 mg/mL of [USP Neodiosmin RS](#) in *Diluent*

Standard solution C: 0.02 mg/mL of [USP Neohesperidin Dihydrochalcone RS](#) from *Standard solution A* in *Diluent*

Sensitivity solution: 0.002 mg/mL of [USP Neohesperidin Dihydrochalcone RS](#) from *Standard solution C* in *Diluent*

Sample solution: 2.0 mg/mL of Neohesperidin Dihydrochalcone in *Diluent*

System suitability

Samples: *System suitability solution*, *Standard solution A*, *Standard solution C*, and *Sensitivity solution*

[NOTE—For the approximate relative retention times of related substances, see [Table 1](#).]

Suitability requirements

Resolution: NLT 2.5 between the neohesperidin dihydrochalcone peak and the neohesperidin dihydrochalcone related compound F peak, *System suitability solution*

Relative standard deviation: NMT 5.0%, determined from the neohesperidin dihydrochalcone peak, *Standard solution C*

Signal-to-noise ratio: NLT 10, determined from the neohesperidin dihydrochalcone peak, *Sensitivity solution*

Chromatogram similarity: The chromatogram obtained from the *Standard solution A* is similar to the reference chromatogram provided with the lot of [USP Neohesperidin Dihydrochalcone RS](#) being used.

Analysis

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

Calculate the percentage of neodiosmin in the portion of Neohesperidin Dihydrochalcone taken:

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

r_U = peak area of neodiosmin from the *Sample solution*

r_S = peak area of neodiosmin from *Standard solution B*

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

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

Calculate the percentage of each impurity except neodiosmin in the portion of Neohesperidin Dihydrochalcone taken:

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

r_U = peak area of each individual impurity except neodiosmin from the *Sample solution*

r_S = peak area of neohesperidin dihydrochalcone from *Standard solution C*

C_S = concentration of [USP Neohesperidin Dihydrochalcone RS](#) in *Standard solution C* (mg/mL)

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

Acceptance criteria: See [Table 1](#).