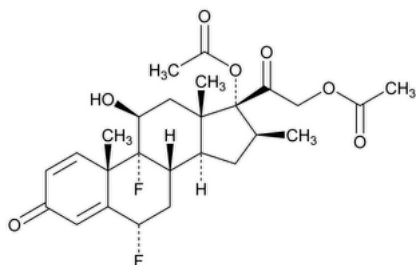


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Diflorasone Diacetate



$C_{26}H_{32}F_2O_7$ 494.52

Pregna-1,4-diene-3,20-dione, 17,21-bis(acetyloxy)-6,9-difluoro-11-hydroxy-16-methyl-, (6 α ,11 β ,16 β)-;

6 α ,9-Difluoro-11 β ,17,21-trihydroxy-16 β -methylpregna-1,4-diene-3,20-dione 17,21-diacetate CAS RN[®]: 33564-31-7; UNII: 7W2J09SCWX.

DEFINITION

Diflorasone Diacetate contains NLT 97.0% and NMT 103.0% of diflorasone diacetate ($C_{26}H_{32}F_2O_7$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- A. [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M▲](#) (CN 1-MAY-2020)

ASSAY

PROCEDURE

Mobile phase: Tetrahydrofuran, glacial acetic acid, water-saturated *n*-butyl chloride, and water-saturated methylene chloride (10:15:350:125)

Internal standard solution: 0.04 mg/mL of isoflupredone acetate in water-saturated chloroform

Standard solution: 33 μ g/mL of [USP Diflorasone Diacetate RS](#) in the *Internal standard solution*

Sample solution: 0.03 mg/mL of Diflorasone Diacetate in the *Internal standard solution*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm \times 10-cm; 3- μ m packing L3

Flow rate: 2.5 mL/min

Injection volume: 10 μ L

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for diflorasone diacetate and the internal standard are 1.0 and 2.4, respectively.]

Suitability requirements

Resolution: NLT 12 between the analyte and the internal standard peaks

Relative standard deviation: NMT 2.0% for NLT four replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of diflorasone diacetate ($C_{26}H_{32}F_2O_7$) in the portion of Diflorasone Diacetate taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak area ratio of diflorasone diacetate and the internal standard from the *Sample solution*

R_S = peak area ratio of diflorasone diacetate and the internal standard from the *Standard solution*

C_S = concentration of [USP Diflorasone Diacetate RS](#) in the *Standard solution* (μ g/mL)

C_U = concentration of Diflorasone Diacetate in the *Sample solution* (μ g/mL)

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.5%

- **ORGANIC IMPURITIES**

Mobile phase and System suitability: Proceed as directed in the Assay.

Sample solution: 6 mg/mL of Diflorasone Diacetate in water-saturated chloroform

Chromatographic system: Proceed as directed in the Assay, except for the following.

Run time: 5 times the retention time of the major peak

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Diflorasone Diacetate taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak area for each impurity

r_T = sum of all the peak areas

Acceptance criteria

Individual impurities: NMT 1.0%

Total impurities: NMT 2.0%

SPECIFIC TESTS

- [LOSS ON DRYING \(731\)](#)

Analysis: Dry under vacuum at 60° at a pressure NMT 5 mm of mercury for 16 h.

Acceptance criteria: NMT 0.5%

- [OPTICAL ROTATION, Specific Rotation \(781S\)](#)

Sample solution: 20 mg/mL of undried Diflorasone Diacetate, in chloroform

Acceptance criteria: +58° to +68°

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

- [USP REFERENCE STANDARDS \(11\)](#)

[USP Diflorasone Diacetate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

| Topic/Question | Contact | Expert Committee |
|----------------------------|---|---------------------------|
| DIFLORASONE DIACETATE | Documentary Standards Support | SM52020 Small Molecules 5 |
| REFERENCE STANDARD SUPPORT | RS Technical Services RSTECH@usp.org | SM52020 Small Molecules 5 |

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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