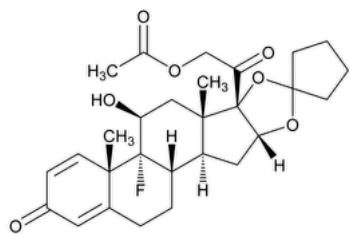


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Amcinonide



$C_{28}H_{35}FO_7$ 502.57
Pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-16,17-[cyclopentylidenebis(oxy)]-9-fluoro-11-hydroxy-, (11 β ,16 α)-;
9-Fluoro-11 β ,16 α ,17,21-tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with cyclopentanone, 21-acetate CAS RN[®]: 51022-69-6;
UNII: 423W026MA9.

DEFINITION

Amcinonide contains NLT 97.0% and NMT 102.0% of amcinonide ($C_{28}H_{35}FO_7$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

Change to read:

- B. [▲]The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*. [▲] (USP 1-Aug-2019)

ASSAY

Change to read:

PROCEDURE

Solution A: Acetonitrile and [water](#) [▲](35:65) [▲] (USP 1-Aug-2019)

Solution B: Acetonitrile and [water](#) [▲](70:30) [▲] (USP 1-Aug-2019)

Mobile phase: See [Table 1](#). Equilibrate the system with *Solution A*.

[▲]Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
2.5	100	0
10	0	100
25	0	100
26	100	0
32	100	0 [▲] (USP 1-Aug-2019)

System suitability solution: 12.5 μ g/mL of [▲][USP Butylparaben RS](#) [▲] (USP 1-Aug-2019) and 20 μ g/mL of [USP Amcinonide RS](#) in *Solution B*

Standard solution: 0.02 mg/mL of [USP Amcinonide RS](#) in *Solution B*

Sample solution: 0.02 mg/mL of Amcinonide in *Solution B*. Sonicate for 5 min.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; ▲5-μm▲ (USP 1-Aug-2019) packing [L1](#)

Flow rate: 2 mL/min

Injection volume: 10 μL

System suitability

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

[NOTE—The relative retention times for butylparaben and amcinonide are 0.78 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 8.0 between butylparaben and amcinonide, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of amcinonide ($C_{28}H_{35}FO_7$) in the portion of Amcinonide 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 Amcinonide RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 97.0%–102.0% on the dried basis

SPECIFIC TESTS

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

Sample solution: 10 mg/mL of Amcinonide in [chloroform](#)

Acceptance criteria: +89.4° to +94.0°

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

Sample: Amcinonide

Analysis: Dry the *Sample* at 105° for 4 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

Change to read:

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

[USP Amcinonide RS](#)

▲ [USP Butylparaben RS](#)▲ (USP 1-Aug-2019)

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

Topic/Question	Contact	Expert Committee
AMCINONIDE	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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