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Amcinonide Cream

DEFINITION

Amcinonide Cream is Amcinonide in a suitable cream base. It contains NLT 90.0% and NMT 115.0% of the labeled amount of amcinonide ($C_{28}H_{35}FO_7$).

IDENTIFICATION

Change to read:

- **A.** ▲The retention time of the amcinonide peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Dec-2019)

ASSAY

Change to read:

• **PROCEDURE**

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

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

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

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

Sample stock solution: Nominally 0.2 mg/mL of amcinonide from Cream prepared as follows. Transfer a quantity of Cream, equivalent to 10 mg of amcinonide, to a 50-mL volumetric flask. Add 5 mL of *Solution B* and 15 mL of [acetonitrile](#), and heat over a steam bath until dissolved. Add 20 mL of *Solution B* while hot, cool to room temperature, dilute with *Solution B* to volume, and refrigerate for 30 min. Vigorously shake the solution to disperse the mixture, and filter while cold. Use the filtrate.

Sample solution: Nominally 0.02 mg/mL of amcinonide from the ▲*Sample stock solution*▲ (USP 1-Dec-2019) in *Solution B*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; ▲5-µm▲ (USP 1-Dec-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 the labeled amount of amcinonide ($C_{28}H_{35}FO_7$) in the portion of Cream 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 = nominal concentration of amcinonide in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

- [MINIMUM FILL \(755\)](#): Meets the requirements

SPECIFIC TESTS

Change to read:

- [MICROBIAL ENUMERATION TESTS \(61\)](#) and [TESTS FOR SPECIFIED MICROORGANISMS \(62\)](#): ▲The total aerobic microbial count is NMT 10^2 cfu/g and the total yeast and mold count is NMT 10^1 cfu/g.▲ (USP 1-Dec-2019) It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

- [pH \(791\)](#): 3.5–5.2

ADDITIONAL REQUIREMENTS

Change to read:

- **PACKAGING AND STORAGE:** Preserve in tight containers.▲Store at controlled room temperature.▲ (USP 1-Dec-2019)

Change to read:

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

[USP Amcinonide RS](#)

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

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

Topic/Question	Contact	Expert Committee
AMCINONIDE CREAM	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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