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Amcinonide Ointment

DEFINITION

Amcinonide Ointment is Amcinonide in a suitable ointment 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-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)

Diluent: Acetonitrile and [chloroform](#) (80:20)

System suitability solution: 12.5 µg/mL of ▲[USP Butylparaben RS](#)▲ (USP 1-Aug-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 prepared as follows. Dissolve a suitable amount of Ointment in a suitable volume of *Diluent* ▲in a volumetric flask▲ (USP 1-Aug-2019) by heating in a hot water bath, cooling, and diluting with *Diluent* to volume. Cool to room temperature, dilute with acetonitrile to volume, and filter.

Sample solution: Nominally 0.02 mg/mL of amcinonide in *Solution B* from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 240 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 the labeled amount of amcinonide ($C_{28}H_{35}FO_7$) in the portion of Ointment 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 yeasts and molds count is NMT 10^1 cfu/g. ▲ (USP 1-Aug-2019) Meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*

ADDITIONAL REQUIREMENTS

Change to read:

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

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 OINTMENT	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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