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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        | <a href="#">Documentary Standards Support</a>                               | SM52020 Small Molecules 5 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br><a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a> | SM52020 Small Molecules 5 |

**Chromatographic Database Information:** [Chromatographic Database](#)

#### Most Recently Appeared In:

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