same retention times obtained from the *Assay preparation* and the *Standard preparation.* Calculate the quantity, in mg, of $C_{24}H_{31}FO_6$ in the portion of Cream taken by the formula:

$$40C(R_U / R_S)$$

in which *C* is the concentration, in mg per mL, of USP Triamcinolone Acetonide RS in the *Standard preparation*, and R_U and R_S are the ratios of the peak heights of triamcinolone acetonide to the internal standard obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Triamcinolone Acetonide Lotion

» Triamcinolone Acetonide Lotion is Triamcinolone Acetonide in a suitable lotion base. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{24}H_{31}FO_6$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩**—**
USP Triamcinolone Acetonide RS

Identification—It responds to the *Identification* test under *Triamcinolone Acetonide Cream.*

Microbial enumeration tests ⟨61⟩ **and Tests for specified microorganisms** ⟨62⟩**—**It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

Minimum fill ⟨755⟩: meets the requirements.

Assay—Proceed with Lotion as directed in the *Assay* under *Triamcinolone Acetonide Cream*, except to read "Lotion" in place of "Cream" throughout.

Triamcinolone Acetonide Ointment

» Triamcinolone Acetonide Ointment is Triamcinolone Acetonide in a suitable ointment base. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of $C_{24}H_{31}FO_6$.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩**—**
USP Triamcinolone Acetonide RS

Identification—Place 2 g of Ointment in a conical flask, add 5.0 mL of chloroform, and shake for 10 minutes. Add 15 mL of alcohol, and shake for an additional 10 minutes. Filter the solution into a centrifuge tube, and evaporate the filtrate to dryness. Dissolve the residue in alcohol to obtain a solution containing about 250 µg per mL. Apply 10 µL of this solution, and 10 µL of a solution of USP Triamcinolone Acetonide RS in alcohol containing 250 µg per mL, on a line parallel to and about 1.5 cm from the bottom edge of a thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel. Place the plate in a developing chamber containing and equilibrated with a mixture of chloroform, benzene, and methanol (100:40:20). Develop the chromatogram until the solvent front has moved about 12 cm above the line of application. Remove the plate, allow the solvent to evaporate, and spray with a mixture of equal volumes of sodium hydroxide solution (1 in 5) and a 1 in 500 solution of blue tetrazolium in methanol: the intensity of the blue color and the R_F of the spot obtained from the solution under test are similar to those of the spot obtained from the Standard solution.

Microbial enumeration tests ⟨61⟩ **and Tests for specified microorganisms** ⟨62⟩**—**It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

Minimum fill ⟨755⟩: meets the requirements.

Assay—Proceed with Ointment as directed in the *Assay* under *Triamcinolone Acetonide Cream*, except to read "Ointment" in place of "Cream" throughout.

Triamcinolone Acetonide Dental Paste

» Triamcinolone Acetonide Dental Paste is Triamcinolone Acetonide in a suitable emollient paste. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of $C_{24}H_{31}FO_6$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩**—**
USP Triamcinolone Acetonide RS

Identification—It responds to the *Identification* test under *Triamcinolone Acetonide Cream.*

Microbial enumeration tests ⟨61⟩ **and Tests for specified microorganisms** ⟨62⟩**—**It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

Minimum fill ⟨755⟩: meets the requirements.

Assay—

Mobile phase—Prepare as directed in the *Assay* under *Triamcinolone Acetonide Cream.*

Internal standard solution and *Standard preparation*—Prepare as directed in the *Assay* under *Triamcinolone Acetonide Cream.*

Assay preparation—Transfer an accurately weighed quantity of Dental Paste, equivalent to about 1.5 mg of triamcinolone acetonide, to a screw-cap tube. Add 20.0 mL of *Internal standard solution*, cap, and place in a sonic bath for 15 to 20 minutes. Place in a water bath at 70° for 5 minutes, then swirl for 1 minute. Repeat the heating and swirling sequence once. Cool in an ice–methanol bath for 15 minutes, then centrifuge for 10 minutes at −5°. Mix an accurately measured volume of the supernatant with an equal volume of *Mobile phase.* Place in an ice–methanol bath for 15 minutes, then centrifuge for 15 minutes. Draw off and discard the upper phase. Filter the lower phase to obtain a clear solution.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Triamcinolone Acetonide Cream.*

Triamcinolone Acetonide Injectable Suspension

DEFINITION

Triamcinolone Acetonide Injectable Suspension is a sterile suspension of Triamcinolone Acetonide in a suitable aqueous medium. It contains NLT 90.0% and NMT 115.0% of the labeled amount of $C_{24}H_{31}FO_6$.

IDENTIFICATION

• **A. Infrared Absorption** ⟨197K⟩

Sample: Extract a volume of Injectable Suspension, equivalent to 50 mg of triamcinolone acetonide, with two 10-mL portions of peroxide-free ether, and discard the ether extracts. Filter with the aid of suction, wash with small portions of water, and dry the precipitate at 105° for 1 h.

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Acceptance criteria: Meets the requirements

- **B. ULTRAVIOLET ABSORPTION** ⟨197U⟩
  Sample solution: 20 µg/mL in methanol, using the triamcinolone acetonide obtained from *Identification* test *A*
  Acceptance criteria: Meets the requirements

ASSAY

- **PROCEDURE**
  Mobile phase: Acetonitrile and water (30:70)
  Internal standard solution: 84 µg/mL of fluoxymesterone in methanol
  Standard stock solution: 200 µg/mL of USP Triamcinolone Acetonide RS in methanol
  Standard solution: 80 µg/mL of USP Triamcinolone Acetonide RS from the *Standard stock solution* diluted with *Internal standard solution*
  Sample stock solution: Dissolve a volume of freshly mixed Injectable Suspension in methanol to obtain a solution containing 200 µg/mL of triamcinolone acetonide.
  Sample solution: 80 µg/mL of triamcinolone acetonide from the *Sample stock solution* diluted with *Internal standard solution*
  Chromatographic system
  (See *Chromatography* ⟨621⟩*, System Suitability*.)
  Mode: LC
  Detector: UV 254 nm
  Column: 4-mm × 30-cm; packing L1
  Flow rate: 1.0 mL/min
  Injection size: 15–25 µL
  System suitability
  Sample: *Standard solution*
  Suitability requirements
  Resolution: NLT 2.0 between triamcinolone acetonide and fluoxymesterone
  Relative standard deviation: NMT 3.0% for five replicate injections
  Analysis
  Samples: *Standard solution* and *Sample solution*
  Calculate the percentage of $C_{24}H_{31}FO_6$ in the portion of Injectable Suspension taken:

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

R_U = peak response ratio of the triamcinolone acetonide peak to the internal standard peak from the *Sample solution*
R_S = peak response ratio of the triamcinolone acetonide peak to the internal standard peak from the *Standard solution*
C_S = concentration of USP Triamcinolone Acetonide RS in the *Standard solution* (mg/mL)
C_U = nominal concentration of triamcinolone acetonide in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

- **UNIFORMITY OF DOSAGE UNITS** ⟨905⟩**:** Meets the requirements

SPECIFIC TESTS

- **BACTERIAL ENDOTOXINS TEST** ⟨85⟩**:** It contains NMT 4.4 USP Endotoxin Units/mg of triamcinolone acetonide.
- **PH** ⟨791⟩**:** 5.0–7.5
- **INJECTIONS** ⟨1⟩**:** Meets the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass, protected from light. Store at controlled room temperature. Do not freeze.
- **USP REFERENCE STANDARDS** ⟨11⟩
  USP Endotoxin RS
  USP Triamcinolone Acetonide RS

Triamcinolone Diacetate

$C_{25}H_{31}FO_8$ 478.51
Pregna-1,4-diene-3,20-dione, 16,21-bis(acetyloxy)-9-fluoro-11,17-dihydroxy-, (11β,16α)-.
9-Fluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione 16,21-diacetate [67-78-7].

» Triamcinolone Diacetate contains not less than 97.0 percent and not more than 103.0 percent of $C_{25}H_{31}FO_8$, calculated on the anhydrous basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩**—**
USP Triamcinolone Diacetate RS

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: *Ultraviolet Absorption* ⟨197U⟩—

Solution: 20 µg per mL.

Medium: dehydrated alcohol.

Absorptivities at 238 nm, calculated on the anhydrous basis, do not differ by more than 3.0%.

Specific rotation ⟨781S⟩: between +39° and +45°.

Test solution: 5 mg per mL, in dimethylformamide.

Water, *Method I* ⟨921⟩: not more than 6.0%.

Residue on ignition ⟨281⟩: not more than 0.5%.

Heavy metals, *Method II* ⟨231⟩: 0.0025%.

Assay—

0.005 M Monobasic sodium phosphate solution—Dissolve monobasic sodium phosphate in water to obtain a solution containing 690 µg per mL.

Mobile phase—Prepare a mixture of *0.005 M Monobasic sodium phosphate solution*, acetonitrile, and tetrahydrofuran (62:37:1), filter through a 0.45-µm solvent-resistant filter, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Triamcinolone Diacetate RS in *Mobile phase*, and dilute quantitatively with *Mobile phase* to obtain a solution having a known concentration of about 40 µg per mL.

Assay preparation—Transfer about 50 mg of Triamcinolone Diacetate, accurately weighed, to a 50-mL volumetric flask, dissolve in *Mobile phase*, dilute with *Mobile phase* to volume, and mix. Pipet 2 mL of this solution into a second 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

System suitability preparation—Dissolve suitable quantities of USP Triamcinolone Diacetate RS and propylparaben in *Mobile phase* to obtain a solution containing about 40 µg per mL and 15 µg per mL, respectively.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *System suitability preparation*, and record the peak responses as directed for *Procedure:* the relative retention times are 1.0 for triamcinolone diacetate and about 1.1 for propylparaben, the resolution, *R,* between the triamcinolone diacetate and propylparaben peaks is not less than 1.7, and the tailing factor, *T,* for the analyte peak is not more than 1.5. Chromatograph replicate injections of the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative standard deviation is not more than 2.0%.

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