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Megestrol Acetate Tablets

DEFINITION
Megestrol Acetate Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of megestrol acetate ($C_{24}H_{32}O_4$).

[Note—Megestrol Acetate Tablets labeled solely for veterinary use are exempt from the requirements of the *Dissolution* test.]

IDENTIFICATION

• **A.**

Sample solution: Grind a suitable number of Tablets in a known volume of chloroform, NLT 10 mL, to obtain a solution containing 4 mg/mL of megestrol acetate.

Analysis: Filter the *Sample solution* into a beaker. Pipet 0.6 mL of the filtrate into a stainless steel grinding vial containing 500 mg of potassium bromide, dry with a current of air, grind, pellet, and record the IR spectrum.

Acceptance criteria: The IR absorption spectrum of the potassium bromide dispersion so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Megestrol Acetate RS.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (55:45)

Diluent: Acetonitrile and water (40:60)

Internal standard solution: 0.8 mg/mL of propylparaben in acetonitrile

Standard stock solution: 1 mg/mL of USP Megestrol Acetate RS in acetonitrile

Standard solution: 80 µg/mL each of USP Megestrol Acetate RS and propylparaben in *Diluent* from the *Standard stock solution* and *Internal standard solution*, respectively

Sample solution: Nominally 80 µg/mL of megestrol acetate prepared as follows. Transfer the equivalent of 80 mg of megestrol acetate from powdered Tablets (NLT 20 Tablets) to a 100-mL volumetric flask. Add 10 mL of water, and shake for 10 min. Add 75 mL of acetonitrile, shake for 30 min, then dilute with acetonitrile to volume. Place a 25-mL aliquot in a glass-stoppered 35-mL centrifuge tube, insert the stopper, and centrifuge for 10 min. Transfer 5.0 mL of the supernatant and 5.0 mL of *Internal standard solution* to a 50-mL volumetric flask, and dilute with *Diluent* to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for propylparaben and megestrol acetate are about 0.4 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 8.0 between propylparaben and megestrol acetate

Relative standard deviation: NMT 2.0% for the peak response ratio of megestrol acetate to propylparaben

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of megestrol acetate ($C_{24}H_{32}O_4$) in the portion of Tablets taken:

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

R_U = peak response ratio of megestrol acetate to propylparaben from the *Sample solution*

R_S = peak response ratio of megestrol acetate to propylparaben from the *Standard solution*

C_S = concentration of USP Megestrol Acetate RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of megestrol acetate in the *Sample solution* (mg/mL)

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• **Disintegration ⟨701⟩**

Sample: Tablets labeled solely for veterinary use; proceed as directed for plain-coated Tablets, but use film-coated Tablets instead.

Time: 30 min

Acceptance criteria: Meet the requirements

• **Dissolution ⟨711⟩**

Medium: 1% sodium lauryl sulfate; 900 mL

Apparatus 2: 75 rpm

Time: 60 min

Standard solution: USP Megestrol Acetate RS in *Medium*

Sample solution: A filtered portion of the solution under test, suitably diluted with *Medium*, if necessary, to a concentration that is similar to that of the *Standard solution.*

Instrumental conditions

Analytical wavelength: UV 292 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the amount of megestrol acetate ($C_{24}H_{32}O_4$) dissolved.

Tolerances: NLT 75% (*Q*) of the labeled amount of megestrol acetate ($C_{24}H_{32}O_4$) is dissolved.

Change to read:

• **Uniformity of Dosage Units ⟨905⟩:** ▲Meet the requirements▲ (CN 1-Aug-2023)

Procedure for content uniformity

Standard solution: 10 µg/mL of USP Megestrol Acetate RS in methanol

Sample solution: Nominally 10 µg/mL of megestrol acetate prepared as follows. Place 1 Tablet in a volumetric flask of suitable size so that the final expected solution concentration is between 0.2 and 1.0 mg of megestrol acetate per mL. Add 1 mL of water, and gently shake until the Tablet has disintegrated. Fill the flask to three-quarters of its nominal capacity with methanol, and shake by mechanical means for 20 min. Dilute with methanol to volume, mix, and filter, discarding the first 15 mL of the filtrate. Dilute 5.0 mL of the subsequent filtrate with methanol.

Instrumental conditions

Mode: UV-Vis

Wavelength range: 260–350 nm

Analytical wavelength: Absorption maximum at about 288 nm

Cell: 1 cm

Blank: Methanol

Analysis

Samples: *Standard solution*,*Sample solution,* and *Blank*

Record the absorbances of the *Standard solution* and the *Sample solution* against the *Blank*, scanning from 260 to 350 nm.

Calculate the percentage of megestrol acetate ($C_{24}H_{32}O_4$) in the Tablet taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Megestrol Acetate RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of megestrol acetate in the *Sample solution* (µg/mL)

▲▲ (CN 1-Aug-2023)

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **Labeling:** Tablets intended solely for veterinary use are so labeled.

• **USP Reference Standards ⟨11⟩**

USP Megestrol Acetate RS

Topic/Question	Contact	Expert Committee
MEGESTROL ACETATE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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