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Guanabenz Acetate Tablets

DEFINITION

Change to read:

Guanabenz Acetate Tablets contain ▲an amount of guanabenz acetate equivalent to▲ (USP 1-May-2019) NLT 90.0% and NMT 110.0% of the labeled amount of guanabenz ($C_8H_8N_4Cl_2$).

IDENTIFICATION

• **A.**

Sample: Transfer an amount of powdered Tablets, equivalent to 8 mg of guanabenz, to a 60-mL separator. Add 10 mL of 0.1 N hydrochloric acid, and shake to disperse the powder. Shake the mixture with three 10-mL portions of chloroform, discarding the chloroform phase each time. Add 5 mL of 1 N sodium hydroxide, and extract with two 25-mL portions of ether, filtering the ether extracts. Evaporate the combined extracts to dryness with the aid of a current of air.

Acceptance criteria: The IR absorption spectrum of a potassium bromide dispersion of the *Sample* exhibits maxima at the same wavelengths as those of a similar preparation of USP Guanabenz Acetate RS.

Add the following:

▲• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-May-2019)

ASSAY

Change to read:

• **Procedure**

Mobile phase: Methanol, phosphoric acid, and water (430:3:570)

Diluent: Dissolve 8.2 g of sodium acetate in 20 mL of water, add 5.7 mL of glacial acetic acid, and dilute with methanol to 1 L.

System suitability solution: Transfer 30 mg of guanabenz acetate to a 100-mL stoppered flask. Add about 50 mL of 0.1 N hydrochloric acid, heat on a steam bath for 60 min, and allow the solution to cool.

Standard solution: 0.1 mg/mL of USP Guanabenz Acetate RS in *Diluent* prepared as follows. Transfer a suitable amount of USP Guanabenz Acetate RS to a suitable volumetric flask. Add 10% of the total volume of water, shake to dissolve the solids, and dilute with *Diluent* to volume.

Sample solution: Nominally 0.08 mg/mL of guanabenz prepared as follows. Transfer 10 Tablets to a 500-mL volumetric flask. Add 50 mL of water, stir by mechanical means until the solids are well dispersed, add 400 mL of *Diluent*, and stir for 45 min. Dilute with *Diluent* to volume, and centrifuge a portion of the mixture until a clear supernatant is obtained. If necessary, dilute a portion of the supernatant quantitatively with a mixture of *Diluent* and water (90:10).

Chromatographic system

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

Mode: LC

Detector: UV 245 nm

Column: ▲3.9-mm▲ (USP 1-May-2019) × 30-cm; ▲10-µm▲ (USP 1-May-2019) packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

▲**Run time:** NLT 6 times the retention time of the guanabenz peak▲ (USP 1-May-2019)

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.6 between guanabenz and the peak eluting before it, *System suitability solution*

Relative standard deviation: NMT 2.0 % *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of guanabenz ($C_8H_8N_4Cl_2$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

M_{r1} = molecular weight of guanabenz, 231.08

M_{r2} = molecular weight of guanabenz acetate, 291.13

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 1000 mL

Apparatus 2: 50 rpm

Time: 60 min

Standard solution: A known concentration of USP Guanabenz Acetate RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter, and dilute with *Medium* to a concentration similar to that of the *Standard solution*.

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: Maximum absorbance at about 272 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentage of the labeled amount of guanabenz ($C_8H_8N_4Cl_2$) dissolved.

Tolerances: NLT 75% (*Q*) of the labeled amount of guanabenz ($C_8H_8N_4Cl_2$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Mobile phase, Diluent, System suitability solution, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Standard solution: Dilute 2 mL of the *Standard solution* from the *Assay* with *Diluent* to 100 mL.

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of any impurity observed having a relative retention time corresponding to the component eluting before guanabenz from the *System suitability solution*.

Acceptance criteria: NMT 2%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Guanabenz Acetate RS

Topic/Question	Contact	Expert Committee
GUANABENZ ACETATE TABLETS	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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