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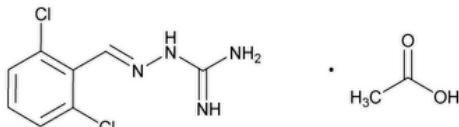
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Guanabenz Acetate



$C_8H_8Cl_2N_4 \cdot C_2H_4O_2$ 291.13

Hydrazinecarboximidamide, 2-[(2,6-dichlorophenyl)methylene]-, monoacetate;

[(2,6-Dichlorobenzylidene)amino]guanidine monoacetate CAS RN®: 23256-50-0; UNII: 443019GK1A.

DEFINITION

Guanabenz Acetate contains NLT 98.0% and NMT 101.5% of the labeled amount of guanabenz acetate ($C_{10}H_{12}N_4O_2Cl_2$).

IDENTIFICATION

Change to read:

- A. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)

ASSAY

- **PROCEDURE**

Sample solution: 4 mg/mL of Guanabenz Acetate in glacial acetic acid

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Potentiometric

Analysis: Titrate 50 mL of the **Sample solution** with **Titrant**. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 29.12 mg of guanabenz acetate ($C_{10}H_{12}N_4O_2Cl_2$).

Acceptance criteria: 98.0%–101.5%

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

- **ORGANIC IMPURITIES**

Diluent: A mixture of formic acid and methanol (1 in 2000)

Aminoguanidine bicarbonate solution: Transfer 100 mg of aminoguanidine bicarbonate to a test tube, add 0.05 mL of formic acid, and warm gently to dissolve. Quantitatively transfer the contents of the test tube to a 10-mL volumetric flask, and dilute with methanol to volume.

Standard solution A: 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, and dissolve in about 50% of total volume of **Diluent**. Add 0.1 mL of **Aminoguanidine bicarbonate solution** per mg of [USP Guanabenz Acetate RS](#), and dilute with **Diluent** to volume.

Standard solution B: 0.05 mg/mL of [USP Guanabenz Acetate RS](#) in **Diluent** from **Standard solution A**

Standard solution C: 0.02 mg/mL of [USP Guanabenz Acetate RS](#) in **Diluent** from **Standard solution A**

Sample solution: 10 mg/mL of Guanabenz Acetate in **Diluent**

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 10 μ L

Analysis**Samples:** Diluent, Standard solution A, Standard solution B, Standard solution C, and Sample solution

Allow the chromatographic chamber to equilibrate in *Developing solvent system* for at least 30 min before use. Prewash a plate coated with *Adsorbent* by placing it in the chromatographic chamber, allowing the solvent front to rise to the top of the plate, dry it in air, and activate it by heating at 105° for 20 min. Within 30 min after preparation, separately apply portions of each of the *Standard solutions*, the *Sample solution*, and the *Diluent*. Allow the spots to dry, and place the plate in the chromatographic chamber. When the solvent has moved about three-fourths of the length of the plate, remove the plate, and allow it to air-dry for about 30 min. Examine the plate under short-wavelength UV light. Estimate the amount of any secondary spots, disregarding spots that have the same R_F as those from the *Diluent*, observed in the chromatogram of the *Sample solution* by comparison with each *Standard solution*. Place the plate in a chamber saturated with iodine vapors for about 10 min. Remove and examine the plate. Estimate the amount of any spot in the chromatogram of the *Sample solution* that has an R_F corresponding to the R_F of the spot produced by the aminoguanidine bicarbonate by comparison with each *Standard solution*.

Acceptance criteria: No individual secondary spot is greater in size or intensity than the spot produced by *Standard solution B* (0.5%), and the total of any such spots observed is NMT 1%.

Change to read:• **LIMIT OF 2,6-DICHLOROBENZALDEHYDE****Internal standard solution 1:** 1 mg/mL of *p*-chlorobenzaldehyde in chloroform**Internal standard solution 2:** 0.1 mg/mL of *p*-chlorobenzaldehyde in chloroform from *Internal standard solution 1***Standard stock solution:** 1 mg/mL of 2,6-dichlorobenzaldehyde in chloroform**Standard solution:** 0.4 mg/mL of 2,6-dichlorobenzaldehyde from the *Standard stock solution* and 0.1 mg/mL of *p*-chlorobenzaldehyde from *Internal standard solution 1* in chloroform**Sample solution:** Transfer 200 mg of Guanabenz Acetate to a 30-mL glass-stoppered centrifuge tube. Add 10 mL of 0.1 N hydrochloric acid, and shake to dissolve. Add 1.0 mL of *Internal standard solution 2*, and shake. Centrifuge, and transfer a portion of the lower layer to a stoppered container. The lower layer must be removed within 10 min of adding the acid to the centrifuge tube.**Chromatographic system**(See [Chromatography \(621\), System Suitability](#).)**Mode:** GC**Detector:** Flame ionization**Column:** ▲1.8-m ▲ (ERR 1-Jun-2019) × 3-mm; packed with 20% phase G1 on 80–100 mesh S1A support**Temperatures****Injection port:** 225°**Detector:** 250°**Column:** 190°**Carrier gas:** Nitrogen**Flow rate:** 30 mL/min**Injection volume:** 2 μ L**System suitability****Sample:** Standard solution[NOTE—The relative retention times for *p*-chlorobenzaldehyde and 2,6-dichlorobenzaldehyde are 0.5 and 1.0, respectively.]**Suitability requirements****Resolution:** NLT 3.0 between 2,6-dichlorobenzaldehyde and *p*-chlorobenzaldehyde**Analysis****Samples:** Standard solution and Sample solution**Acceptance criteria:** The relative peak response ratio from the *Sample solution* does not exceed that from the *Standard solution* (0.2%).**SPECIFIC TESTS**• [pH \(791\)](#)**Sample solution:** 7 mg/mL**Acceptance criteria:** 5.5–7.0• [Loss on Drying \(731\)](#)**Analysis:** Dry under vacuum at 60° for 2 h.**Acceptance criteria:** NMT 1.0%

<https://trungtamthuoc.com>

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

• **USP REFERENCE STANDARDS (11):**

[USP Guanabenz Acetate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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