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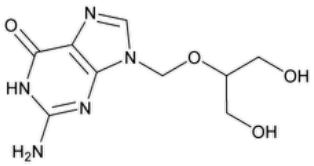
Ganciclovir



$C_9H_{13}N_5O_4$ 255.23

6*H*-Purin-6-one, 2-amino-1,9-dihydro-9-[[2-hydroxy-1-(hydroxymethyl)ethoxy]methyl]-;

9-[[2-Hydroxy-1-(hydroxymethyl)ethoxy]methyl]guanine CAS RN®: 82410-32-0; UNII: P9G3CKZ4P5.

DEFINITION

Ganciclovir contains NLT 98.0% and NMT 102.0% of $C_9H_{13}N_5O_4$, calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

Change to read:

• **B.** ▲Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: **197U**▲ (CN 1-May-2020)

Sample solution: 10 µg/mL in methanol

ASSAY

• **Procedure**

Solution A: Trifluoroacetic acid and water (0.5 in 1000)

Mobile phase: Acetonitrile and *Solution A* (1:1)

System suitability solution: 0.1 mg/mL each of USP Ganciclovir RS and USP Ganciclovir Related Compound A RS in *Mobile phase*. [Note—Sonicate the solution if necessary.]

Standard solution: 0.22 mg/mL of USP Ganciclovir RS in *Mobile phase*

Sample solution: 0.22 mg/mL of Ganciclovir in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L9

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection size: 20 µL

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for ganciclovir related compound A and ganciclovir are 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.4 between ganciclovir and ganciclovir related compound A

Column efficiency: NLT 5000 theoretical plates

Tailing factor: NMT 1.4

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_9H_{13}N_5O_4$ in the portion of Ganciclovir 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 Ganciclovir RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

Inorganic Impurities

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

Organic Impurities

• **Procedure**

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

Sample solution: 0.22 mg/mL of Ganciclovir in *Mobile phase*

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Ganciclovir taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response for each impurity in the *Sample solution*

r_T = sum of the responses of all the peaks

Acceptance criteria

Ganciclovir related compound A: NMT 0.5%

Total impurities: NMT 1.5%

SPECIFIC TESTS

• **Water Determination, *Method I*⟨921⟩:** NMT 6.0%

[Note—Ganciclovir is extremely hygroscopic.]

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Store at 25°, excursions permitted between 15° and 30°.

• **USP Reference Standards ⟨11⟩**

USP Ganciclovir RS

USP Ganciclovir Related Compound A RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
GANCICLOVIR	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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