Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Dec-2016
Document Type: USP Monographs
DocId: GUID-7122BF87-D1AA-412C-9526-9F792986A75D_1_en-US
DOI: https://doi.org/10.31003/USPNF_M1389_01_01
DOI Ref: o1hwg

Ganciclovir Compounded Oral Suspension

DEFINITION

Ganciclovir Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of ganciclovir ($C_9H_{13}N_5O_4$).

Prepare Ganciclovir Compounded Oral Suspension 100 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Ganciclovir	10 g
Vehicle for Oral Solution (regular or sugar-free), *NF*, a sufficient quantity to make	100 mL

Add sufficient *Vehicle for Oral Solution* to wet the *Ganciclovir* powder, and triturate to form a smooth paste. Add additional *Vehicle for Oral Solution* to about half the final volume, and transfer the contents of the mortar to a calibrated bottle. Using additional *Vehicle for Oral Solution*, rinse the mortar, and transfer the contents, stepwise and quantitatively, to bring to final volume. Mix well.

[**Caution—**Avoid skin contact or inhalation of ganciclovir by using protective gloves and a fume hood or surgical mask.]

ASSAY

• **Procedure**

Solution A: 25-mM monobasic sodium phosphate solution. Adjust with phosphoric acid to a pH of 2.5.

Mobile phase: Acetonitrile and *Solution A* (2.5:97.5). Filter and degas.

Internal standard solution: 0.4 mg/mL of hypoxanthine

Standard stock solution: 1.0 mg/mL of USP Ganciclovir RS

Standard solution: 6 µg/mL of ganciclovir and 4 µg/mL of hypoxanthine prepared from *Standard stock solution* and *Internal standard solution*

Sample solution: Transfer about 1 mL of Oral Suspension from each bottle to a plastic weighing cup, and weigh to determine density. [Note—The exact volume of Oral Suspension taken from each bottle is calculated by the suspension density.] Transfer the Oral Suspension to a 100-mL volumetric flask, and add 50 mL of water. Place the volumetric flask on a mechanical shaker for 30 min, and dilute with water to volume. Transfer 0.6 mL of this solution and 1 mL of the *Internal standard solution* to a 100-mL volumetric flask, and dilute with water to volume to obtain a solution with a nominal concentration of 6 µg/mL of ganciclovir and 4 µg/mL of hypoxanthine.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 10-cm; 5-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for hypoxanthine and ganciclovir are 0.75 and 1.0, respectively.]

Suitability requirements

Relative standard deviation: NMT 1.5% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ganciclovir ($C_9H_{13}N_5O_4$) in the portion of Oral Suspension taken:

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

R_U = peak response ratio of ganciclovir to the internal standard from the *Sample solution*

R_S = peak response ratio of ganciclovir to the internal standard from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.0–5.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature

• **Labeling:** Label it to state that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Ganciclovir RS

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

Topic/Question	Contact	Expert Committee
GANCICLOVIR COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(6)

Current DocID: GUID-7122BF87-D1AA-412C-9526-9F792986A75D_1_en-US

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