• **LABELING:** Label it to state that it is to be handled with great care because it is a potent cytotoxic agent and suspected carcinogen.

Change to read:

• **USP REFERENCE STANDARDS** ⟨11⟩
• (CN 1-May-2018)
USP Ganciclovir RS

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

Absorbent Gauze

» Absorbent Gauze is cotton, or a mixture of cotton, and not more than 53.0 percent, by weight, of rayon, and is in the form of a plain woven cloth conforming to the standards set forth herein. Absorbent Gauze that has been rendered sterile is packaged to protect it from contamination.
[NOTE—Condition all Absorbent Gauze for not less than 4 hours in a standard atmosphere of 65 ± 2% relative humidity at 21 ± 1.1° before determining the weight, thread count, and absorbency. Remove the Absorbent Gauze from its wrappings before placing it in the conditioning atmosphere, and if it is in the form of bolts or rolls, cut the quantity necessary for the various tests from the piece, excluding the first two and the last two meters when the total quantity of Gauze available so permits.]

Packaging and storage—Preserve in well-closed containers. Absorbent Gauze that has been rendered sterile is so