

## Temozolomide Suspension 10 mg/mL

### INGREDIENTS:

Temozolomide 100 mg capsule	12 capsules
Anhydrous citric acid powder	30 mg
Povidone K-30 powder	600 mg
Purified water USP	1.8 mL
Ora-Plus	60 mL
Ora-Sweet	QSAD: 120 mL

### EQUIPMENT AND SUPPLIES:

Containment ventilated enclosure (CVE) or biological safety cabinet (BSC), pharmaceutical analytical scale, glass mortar and pestle, graduated cylinder

### PREPARATION DETAILS:

**Caution: Hazardous Drug—Antineoplastic drug: Must be prepared in compliance with USP <800>.**

1. Open capsules and empty contents into a mortar.
2. Weigh povidone K-30 powder and place in mortar.
3. Triturate contents to a fine powder.
4. Dissolve anhydrous citric acid in purified water.
5. Levigate powder with anhydrous citric acid solution to form a paste.
6. Add Ora-Plus in increasing amounts while mixing thoroughly.
7. Transfer contents of the mortar to a graduated cylinder.
8. Rinse the mortar and pestle with vehicle and pour into graduated cylinder.
9. Add vehicle to the graduated cylinder to achieve the total volume indicated above.
10. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
11. Shake well to mix.

**Alternatives** — May substitute vehicle with Ora-Sweet SF. Stable for 60 days when refrigerated and 14 days when stored at room temperature.

**Quality-Control Procedures** — Visually inspect for physical appearance of formulation and container closure integrity (no leakage, cracks in container, or improper seals).

**Labeling Requirements** — Extemporaneously compounded preparation. Caution: antineoplastic drug. For oral use only. Store at room temperature or refrigerate. Shake well before use.

**Storage Conditions/Stability** — Store at room temperature or refrigerate. Stable for 60 days when refrigerated and 7 days when stored at room temperature.

## Temozolomide Suspension 10 mg/mL (continued)

### STABILITY STUDY DETAILS:

**Study Container Type** — Amber plastic (polyethylene terephthalate [PET]) screw-cap prescription bottle

**Referenced Manufacturers** — Temozolomide capsules (Schering); Ora-Plus, Ora-Sweet, Ora-Sweet SF (Paddock Laboratories, LLC); povidone K-30 powder (Spectrum Chemical Manufacturing Corp); anhydrous citric acid powder (Fisher Chemical); purified water (not specified).

**Stability-Indicating Study** — Yes

### REFERENCE

1. Trissel LA, Zhang Y, Koontz SE. Temozolomide stability in extemporaneously compounded oral suspensions. *Int J Pharm Compd.* 2006;10:396-399.