

Erlotinib Suspension 10 mg/mL

INGREDIENTS:

Erlotinib 150 mg tablet	8 tablets
Ora-Plus	60 mL
Ora-Sweet	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

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

PREPARATION DETAILS:

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

1. Triturate tablets to a fine powder with a mortar and pestle.
2. Levigate powder with Ora-Plus to form paste.
3. Add Ora-Plus in increasing amounts while mixing thoroughly.
4. Transfer contents of the mortar to a graduated cylinder.
5. Rinse the mortar and pestle with vehicle and pour into graduated cylinder.
6. Add vehicle to the graduated cylinder to achieve the total volume indicated above.
7. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
8. Shake well to mix.

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. Shake well before use.

Storage Conditions/Stability — Store at room temperature. Stable for 28 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber polypropylene prescription bottle

Referenced Manufacturers — Erlotinib tablets (Kremers Urban Pharmaceuticals, Inc); Ora-Plus, Ora-Sweet (Perrigo Co).

Stability-Indicating Study — No

REFERENCE

1. Li Q, Liu Z, Kolli S, et al. Stability of extemporaneous erlotinib, lapatinib, and imatinib oral suspensions. *Am J Health Syst Pharm.* 2016;73(17):1331-1337.