

Glycopyrrolate Suspension 0.5 mg/mL—Formulation 1

INGREDIENTS:

Glycopyrrolate 1 mg tablet	60 tablets
Ora-Plus/Ora-Sweet*	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, glass mortar and pestle, graduated cylinder

PREPARATION DETAILS:

1. Triturate tablets to a fine powder with a mortar and pestle.
2. Levigate powder with a small amount of vehicle to form a paste.
3. Add vehicle 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.

Special Instructions — *Mix 60 mL of Ora-Plus with 60 mL of Ora-Sweet. Use mixture as vehicle or use Ora-Blend. Bitter aftertaste. May administer chocolate syrup before medication administration or mix the preparation with chocolate syrup (1:1 by volume) immediately before administration to mask the bitter aftertaste.

Alternatives — May substitute vehicle with 60 mL of Ora-Plus mixed with 60 mL of Ora-Sweet SF or Ora-Blend SF.

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. For oral use only. Store at room temperature. Shake well before use.

Storage Conditions/Stability — Store at room temperature. Stable for 90 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber plastic prescription bottle with child-resistant cap

Referenced Manufacturers — Glycopyrrolate tablets (Corepharma, LLC); Ora-Plus, Ora-Sweet, Ora-Sweet SF (Paddock Laboratories, LLC).

Stability-Indicating Study — Yes

Commercially available as a 0.2-mg/mL solution — Use extemporaneously prepared formulation only when commercial product is unavailable or a more concentrated suspension is desired.

REFERENCE

1. Cober MP, Johnson CE, Sudekum D, et al. Stability of extemporaneously prepared glycopyrrolate oral suspensions. *Am J Health Syst Pharm.* 2011;68:843-845.