

Carvedilol Suspension 0.1 mg/mL

INGREDIENTS:

Carvedilol 3.125 mg tablet	4 tablets
Purified water USP	20 mL
Ora-Plus	60 mL
Ora-Sweet	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, mortar and pestle, graduated cylinder

PREPARATION DETAILS:

1. Triturate tablets to a fine powder with a mortar and pestle.
2. Levigate powder with purified water to form a 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. For oral use only. Store at room temperature. Shake well before use.

Storage Conditions/Stability — Store at room temperature. Stable for 84 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber glass bottle

Referenced Manufacturers — Carvedilol tablets (Coreg, GlaxoSmithKline); Ora-Plus, Ora-Sweet (Paddock Laboratories, LLC); purified water (not specified).

Stability-Indicating Study — No

REFERENCES

1. GlaxoSmithKline, Philadelphia, PA: Data on file; 2007. EC2007/00022/01.
2. GlaxoSmithKline, Philadelphia, PA: Data on file; 2007. EC2007/00010/00.