

Codeine Phosphate Syrup 3 mg/mL

INGREDIENTS:

Codeine phosphate powder USP	360 mg
Sterile water for irrigation	1.5 mL
Ora-Sweet	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, pharmaceutical analytical scale, mortar and pestle, graduated cylinder

PREPARATION DETAILS:

1. Weigh out powder and add to a mortar.
2. Triturate contents to a fine powder.
3. Levigate powder with sterile water for irrigation to form a paste.
4. Add vehicle in increasing amounts while mixing thoroughly.
5. Transfer contents of the mortar to a graduated cylinder.
6. Rinse the mortar and pestle with vehicle and pour into graduated cylinder.
7. Add vehicle to the graduated cylinder to achieve the total volume indicated above.
8. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
9. 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 98 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber polyethylene terephthalate (PET) bottle with child-resistant cap and 5-mL amber polyethylene oral syringe with silicon elastomer tip sealed with high-density polyethylene syringe cap

Referenced Manufacturers — Codeine phosphate powder USP (Spectrum Chemical Manufacturing Corp); sterile water for irrigation USP (Hospira); Ora-Sweet (Paddock Laboratories, LLC).

Stability-Indicating Study — Yes

REFERENCE

1. Dentinger PJ, Swenson CF. Stability of codeine phosphate in an extemporaneously compounded syrup. *Am J Health Syst Pharm.* 2007;64(24):2569-2573.