

## Melatonin 1 mg/mL and Pyridoxine Hydrochloride 3.3 mg/mL Suspension

### INGREDIENTS:

Melatonin 3 mg and pyridoxine hydrochloride 10 mg tablet 40 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.

**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 bottle with child-resistant cap

**Referenced Manufacturers** — Melatonin/pyridoxine tablets (Natrol, Inc); Ora-Plus, Ora-Sweet, Ora-Sweet SF (Paddock Laboratories, LLC).

**Stability-Indicating Study** — Yes

**Footnote** — Only stability of melatonin was tested. Stability of pyridoxine hydrochloride was not tested.

### REFERENCE

1. Johnson CE, Cober MP, Thome T, et al. Stability of an extemporaneous alcohol-free melatonin suspension. *Am J Health Syst Pharm.* 2011;68(5):420-423.