

Sotalol Hydrochloride Suspension 5 mg/mL

INGREDIENTS:

Sotalol hydrochloride 120 mg tablet	5 tablets
Ora-Plus/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 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 12 mL 1% methylcellulose (see page 107 for preparation directions) mixed with 108 mL simple syrup NF or SyrSpend SF PH4. Stable for 90 days when refrigerated or stored at room temperature.

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 or refrigerate. Shake well before use.

Storage Conditions/Stability — Store at room temperature or refrigerate. Stable for 91 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber plastic prescription bottle¹; low-actinic, light-resistant prescription bottle²

Referenced Manufacturers — Sotalol hydrochloride tablets (Berlex Laboratories, Inc); Ora-Plus, Ora-Sweet (Paddock Laboratories, LLC); methylcellulose (not specified); simple syrup (Humco).¹ Sotalol hydrochloride tablets (not specified); SyrSpend SF PH4 (Fagron).²

Stability-Indicating Study — Yes

Commercially available — Use extemporaneously prepared formulation only when commercial product is unavailable.

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Sotalol Hydrochloride Suspension 5 mg/mL (continued)

REFERENCES

1. Nahata MC, Morosco RS. Stability of sotalol in two liquid formulations at two temperatures. *Ann Pharmacother*. 2003;37(4):506-509.
2. Polonini H, da Silva SL, Brandão MAF, et al. Compatibility of baclofen, carvedilol, hydrochlorothiazide, mercaptopurine, methadone hydrochloride, oseltamivir phosphate, phenobarbital, propranolol hydrochloride, pyrazinamide, sotalol hydrochloride, spironolactone, tacrolimus monohydrate, ursodeoxycholic acid, and vancomycin hydrochloride oral suspensions compounded with SyrSpend SF pH4. *Int J Pharm Compd*. 2018;22(6):516-526.