

Labetalol Hydrochloride Suspension 40 mg/mL— Formulation 2

INGREDIENTS:

Labetalol hydrochloride 200 mg tablet	24 tablets
SyrSpend SF PH4	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.

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 90 days.

STABILITY STUDY DETAILS:

Study Container Type — Not specified.

Referenced Manufacturers — Labetalol hydrochloride tablets (Trandate, Kern Pharma); SyrSpend SF PH4 (Fagron).

Stability-Indicating Study — Yes

REFERENCE

1. Uriel M, Gómez-Rincón C, Marro D. Stability of regularly prescribed oral liquids formulated with SyrSpend® SF. *Pharmazie*. 2018;73(4):196-201.