

Labetalol Hydrochloride Syrup 10 mg/mL

INGREDIENTS:

Labetalol hydrochloride 100 mg tablet	12 tablets
Simple syrup NF	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, mortar and pestle, graduated cylinder, coarse filter, 0.45- μ m filter

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. Filter solution through a coarse filter and then through a 0.45- μ m filter.
9. Shake well to mix.

Alternatives — May substitute vehicle with distilled water, apple juice, grape juice, or orange juice.

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 28 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber plastic oval and amber glass oval (only stored at room temperature)

Referenced Manufacturers — Labetalol hydrochloride tablets (Trandate, Glaxo Inc); simple syrup (Humco); distilled water (not specified); apple juice, orange juice (Cost Cutter); grape juice (Kroger).

Stability-Indicating Study — No

REFERENCE

1. Nahata MC. Stability of labetalol hydrochloride in distilled water, simple syrup, and three fruit juices. *DICP*. 1991;25(5):465-469.