Imipramine Hydrochloride Suspension 5 mg/mL

INGREDIENTS:

Imipramine hydrochloride powder	600 mg
SyrSpend SF PH4	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 a small amount of vehicle 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 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 — Low-actinic, light-resistant prescription bottle

Referenced Manufacturer — Imipramine hydrochloride powder, SyrSpend SF PH4 (Fagron).

Stability-Indicating Study — Yes

REFERENCE

1. Polonini HC, Silva SL, Cunha CN, et al. Compatibility of cholecalciferol, haloperidol, imipramine hydrochloride, levodopa/carbidopa, lorazepam, minocycline hydrochloride, tacrolimus monohydrate, terbinafine, tramadol hydrochloride and valsartan in SyrSpend SF PH4 oral suspensions. *Pharmazie*. 2016;71(4):185-191.

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