Dapsone Syrup 2 mg/mL

INGREDIENTS:

Dapsone 25 mg tablet	8 tablets
Citric acid crystals	500 mg
Distilled water	25 mL
Simple syrup NF	QSAD: 100 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, pharmaceutical analytical scale, mortar and pestle, graduated cylinder

PREPARATION DETAILS:

1. Triturate tablets to a fine powder with a mortar and pestle.
2. Dissolve citric acid crystals in the volume of distilled water indicated above.
3. Levigate powder with citric acid solution 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 91 days.**

STABILITY STUDY DETAILS:

Study Container Type — Amber polyethylene terephthalate (PET) prescription bottle

Referenced Manufacturers — Dapsone tablets (Jacobus Pharmaceutical Co); citric acid crystals, simple syrup (Humco); distilled water (Magnetic Springs Bottled Water Co).

Stability-Indicating Study — Yes

REFERENCE

1. Nahata MC, Morosco RS, Trowbridge JM. Stability of dapsone in two oral liquid dosage forms. *Ann Pharmacother*. 2000;34(7-8):848-850.

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