

Ketoconazole Suspension 20 mg/mL—Formulation 2

INGREDIENTS:

Ketoconazole powder	2.4 g
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 prescription bottle

Referenced Manufacturers — Ketoconazole powder (Pharma Nostra); SyrSpend SF PH4 (Fagron).

Stability-Indicating Study — Yes

REFERENCE

1. Polonini HC, Loures S, de Araujo EP, et al. Stability of allopurinol, amitriptyline hydrochloride, carbamazepine, domperidone, isoniazid, ketoconazole, lisinopril, naproxen, paracetamol (acetaminophen), and sertraline hydrochloride in SyrSpend SF PH4 oral suspension. *Int J Pharm Compd.* 2016;20:426-434.