

Itraconazole Suspension 20 mg/mL—Formulation 2

INGREDIENTS:

Itraconazole 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 — Not specified.

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

Stability-Indicating Study — Yes

Commercially available as a 10-mg/mL solution — Use extemporaneously prepared formulation only when commercial product is unavailable or a more concentrated suspension is desired. Extemporaneously prepared suspension may not achieve same bioavailability as commercially available formulation. Monitoring of serum itraconazole concentration may be warranted.

REFERENCES

1. Uriel M, Gómez-Rincón C, Marro D. Stability of regularly prescribed oral liquids formulated with SyrSpend® SF. *Pharmazie*. 2018;73(4):196-201.
2. Villarreal JD, Erush SC. Bioavailability of itraconazole from oral liquids in question. *Am J Health Syst Pharm*. 1995;52(15):1707-1708.
3. Christensen KJ, Gubbins PO, Gurley BJ, et al. Relative bioavailability of itraconazole from an extemporaneously prepared suspension and from the marketed capsules. *Am J Health Syst Pharm*. 1998;55:261-265.