

Itraconazole Suspension 20 mg/mL—Formulation 1

INGREDIENTS:

Itraconazole 100 mg capsule	20 capsules
Ethyl alcohol USP	7.5 mL
Ora-Plus/Ora-Sweet*	QSAD: 100 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, mortar and pestle, graduated cylinder

PREPARATION DETAILS:

1. Open capsules and empty contents into a mortar.
2. Add alcohol to beads and let it stand for 3 to 4 minutes to soften the beads.
3. Triturate beads to a fine powder.
4. Levigate powder with a small amount of vehicle to form a paste.
5. Add vehicle in increasing amounts while mixing thoroughly.
6. Transfer contents of the mortar to a graduated cylinder.
7. Rinse the mortar and pestle with vehicle and pour into graduated cylinder.
8. Add vehicle to the graduated cylinder to achieve the total volume indicated above.
9. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
10. Shake well to mix.

Special Instructions — *Mix 50 mL of Ora-Plus with 50 mL of Ora-Sweet. Use mixture as vehicle or use Ora-Blend.

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 56 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber plastic prescription bottle

Referenced Manufacturers — Itraconazole capsules (Sporanox, Janssen Pharmaceuticals); alcohol (not specified); Ora-Plus, Ora-Sweet (Paddock Laboratories, LLC).

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.

Itraconazole Suspension 20 mg/mL—Formulation 1 (continued)

REFERENCES

1. Abdel-Rahman SM, Nahata MC. Stability of itraconazole in an extemporaneous suspension. *J Ped Pharm Pract.* 1998;3:115-118.
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.