

Diazoxide Suspension 10 mg/mL—Formulation 2

INGREDIENTS:

Diazoxide powder	1.2 g
Glycerin USP	1.8 mL
Oral Mix	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 glycerin 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.

Alternatives — May substitute vehicle with Oral Mix SF.

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 — Amber polyethylene terephthalate (PET) bottle with black phenolic cap and 1-mL amber plastic oral syringe with tip cap

Referenced Manufacturer — Diazoxide powder, glycerin USP, Oral Mix, Oral Mix SF (Medisca).

Stability-Indicating Study — Yes

Commercially available as a 50-mg/mL suspension — Use extemporaneously prepared formulation only when commercial product is unavailable or a more dilute suspension is desired.

REFERENCE

1. Friciu M, Zarea S, Roullin VG, et al. Stability of diazoxide in extemporaneously compounded oral suspensions. *PLoS One*. 2016;11(10):e0164577. doi:10.1371/pone.0164577.