

Mycophenolate Mofetil Suspension 50 mg/mL

INGREDIENTS:

Mycophenolate mofetil 250 mg capsule	24 capsules
Ora-Plus	30 mL
Cherry syrup	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Containment ventilated enclosure (CVE) or biological safety cabinet (BSC), mortar and pestle, graduated cylinder

PREPARATION DETAILS:

Caution: Hazardous Drug—Non-antineoplastic hazardous drug: Must be prepared in compliance with USP <800>.

1. Open capsules and empty contents into a mortar.
2. Triturate contents to a fine powder.
3. Levigate powder with Ora-Plus to form 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. Caution: hazardous drug. 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 50 days when refrigerated and 28 days when stored at room temperature.

STABILITY STUDY DETAILS:

Study Container Type — Amber bottle

Referenced Manufacturer — Not specified.

Stability-Indicating Study — Yes

Commercially available as a 200-mg/mL suspension — Use extemporaneously prepared formulation only when commercial product is unavailable or a more dilute suspension is desired.

REFERENCE

1. Venkataramanan R, McCombs JR, Zuckerman S, et al. Stability of mycophenolate mofetil as an extemporaneous suspension. *Ann Pharmacother.* 1998;32:755-757.