Cyclophosphamide Suspension 10 mg/mL

INGREDIENTS:

Cyclophosphamide 2 g injection	1 vial
Sodium chloride 0.9% for injection	100 mL
Ora-Plus	QSAD: 200 mL

EQUIPMENT AND SUPPLIES:

Containment ventilated enclosure (CVE) or biological safety cabinet (BSC), 2 × 18-G needles, 2 × 60-mL syringes, graduated cylinder

PREPARATION DETAILS:

Caution: Hazardous Drug—Antineoplastic drug: Must be prepared in compliance with USP <800>.

1. Reconstitute injectable powder with 100 mL of sodium chloride 0.9% injection.
2. Withdraw volume of injectable solution using two 60-mL syringes.
3. Transfer solution to a graduated cylinder.
4. Add vehicle to the graduated cylinder to achieve the total volume indicated above.
5. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
6. Shake well to mix.

Alternatives — May substitute vehicle with simple syrup.

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: antineoplastic drug. For oral use only. Store in refrigerator. Shake well before use.

Storage Conditions/Stability — **Refrigerate. Stable for 56 days.**

STABILITY STUDY DETAILS:

Study Container Type — Amber polypropylene oral syringe

Referenced Manufacturers — Cyclophosphamide injection, sodium chloride 0.9% for injection (Baxter); Ora-Plus (Paddock Laboratories, LLC); simple syrup (Humco).

Stability-Indicating Study — Yes

REFERENCE

1. Kennedy R, Groepper D, Tagen M, et al. Stability of cyclophosphamide in extemporaneous oral suspensions. *Ann Pharmacother*. 2010;44(2):295-301.

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