

Hydroxyurea Syrup 100 mg/mL*

INGREDIENTS:

| | |
|------------------------------|--------------|
| Hydroxyurea 500 mg capsule | 24 capsules |
| Sterile water for irrigation | 60 mL |
| Syrpalta, dye free | QSAD: 120 mL |

EQUIPMENT AND SUPPLIES:

Containment ventilated enclosure (CVE) or biological safety cabinet (BSC), graduated cylinder, beaker, magnetic stirrer, filter

PREPARATION DETAILS:

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

1. Open capsules and empty contents into a beaker.
2. Add sterile water for irrigation in increasing amounts while mixing thoroughly.
3. Vigorously stir for several hours using a magnetic stirrer.
4. Filter solution to remove insoluble excipients.
5. Transfer contents of the beaker to a graduated cylinder.
6. Rinse the beaker 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: antineoplastic drug. For oral use only. Store at room temperature. Shake well before use.

Storage Conditions/Stability — Store at room temperature. Stable for 180 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber plastic bottle

Referenced Manufacturers — Hydroxyurea capsules (Hydrea, Bristol-Myers Squibb); Syrpalta, dye-free (Humco); sterile water for irrigation (not specified).

Stability-Indicating Study — No

REFERENCE

1. Heeney MM, Whorton MR, Howard TA, et al. Chemical and functional analysis of hydroxyurea oral solutions. *J Pediatr Hematol Oncol.* 2004;26:179-184.