

Busulfan Syrup 2 mg/mL

INGREDIENTS:

Busulfan 2 mg tablet	120 tablets
Simple syrup NF	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—Antineoplastic drug: Must be prepared in compliance with USP <800>.

1. Triturate tablets to a fine powder with a mortar and pestle.
2. Levigate powder with a small amount of vehicle to form a paste.
3. Add vehicle in increasing amounts while mixing thoroughly.
4. Transfer contents of the mortar to a graduated cylinder.
5. Rinse the mortar and pestle with vehicle and pour into graduated cylinder.
6. Add vehicle to the graduated cylinder to achieve the total volume indicated above.
7. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
8. 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 in refrigerator. Shake well before use.

Storage Conditions/Stability — Refrigerate. Stable for 30 days.

STABILITY STUDY DETAILS:

Study Container Type — Tight, light-resistant container

Referenced Manufacturer — Busulfan tablets (Myleran, Burroughs Wellcome Co); simple syrup (not specified).

Stability-Indicating Study — No

REFERENCES

1. Partin JM, Poust RI, Cox FO. Stability of busulfan in suspension. *Pharm Res.* 1988;5:S-74.
2. Allen LV Jr. Busulfan oral suspension. *US Pharm.* 1990;15:94-95.