



---

Calcium Gluconate 0.46-mEq/ mL Sterile Injection

Version number: 1.0

Volume: 100 mL

---

Calcium Gluconate, USP	10gm
Calcium Saccharate (Tetrahydrate), USP (C1830)	0.455gm
Hydrochloric Acid, Diluted (10% or 0.1N)	PRN
Sodium Hydroxide 10% Aqueous Solution	PRN
Sterile Water for Injection (Preservative-free)	Q.S. 100mL

---

This compound should be prepared in an ISO Class 5 environment by a licensed pharmacist or supervised pharmacy technician trained in proper aseptic technique. Review USP <797> and check with your state board(s) of pharmacy to ensure proper compliance with regulations on the preparation of CSPs. Personnel assessments, sterility, potency and endotoxin levels testing should be outlined in the pharmacy SOPs.

#### **SUGGESTED COMPOUNDING PROCEDURES**

1. Calculate the required quantity of each ingredient for the total amount to be prepared
2. Accurately weigh and/or measure each ingredient
3. Dissolve the calcium gluconate and the calcium saccharate tetrahydrate in about 90mL of sterile water for injection
4. Check the pH and adjust to pH 6.0 to 8.2 with hydrochloric acid or calcium hydroxide solution and record results
5. Add sufficient sterile water for injection to volume and mix well
6. Using a 0.2µm filter, filter into sterile, depyrogenated vials, stopper with sterilized stoppers, apply seal, crimp and label.
7. Suggested Quality Assessments – follow pharmacy SOPs:
  - a. Bubble point filter integrity
  - b. Particulate
  - c. Sterility
  - d. Endotoxin
  - e. Label - Auxiliary labels, Refrigerate or Freeze, BUD, compounded medication

Protect from light

Note: According to USP Chapter <797>, in the absence of passing a sterility test the storage periods for compounded sterile preparations (high risk) cannot exceed the following time periods:

Controlled Room Temperature: not more than 24 hours

Cold Temperature: not more than 3 days

Refer to USP chapter <797>.

No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

Beyond-Use Dates of preparations are conservative estimates by the formulator using reference books, peer-reviewed literature, intended duration of therapy, formulation from commercially available products, organoleptic observations and current USP guidelines. Compounders may have stability studies performed by a reputable laboratory if they wish to extend the Beyond-Use Date. It is recommended that you follow USP <795> recommendations for potency testing.

**Beyond-Use Date for batches of injections that have passed sterility testing is estimated to be up to 14 days, stored in a refrigerator, from the original date of compound per *Compounding Today.com***

Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. Wear appropriate protective equipment. Use safety enclosures (hoods) when weighing and mixing.

4/18 JD