SUGGESTED FORMULA

Corticotrophin Injection 80 units/mL
Version number: 1.0
Volume: 100 mL

Corticotrophin	8,000 Units
Liquified Phenol, USP	0.6 mL
Dextrose, USP	4.372 gm
Hydrochloric Acid 10%	pH
Water for Injection	50 mL
Sodium Carboxymethylcellulose, Gel 2.5%	50 mL

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. Measure corticotrophin, liquified phenol, and dextrose and dissolve in 90% of volume of water for injection in depyrogenated, calibrated container and mix thoroughly.
2. Using hydrochloric acid solution adjust pH to 5-6 and QS to volume with water (1/2 total volume prepared)
3. Prepare sodium carboxymethylcellulose (SCMC) gel 2.5% using medium viscosity, USP SCMC and sterile water for injection, sterilize by autoclaving, and allow gel to hydrate for 24 hours.
4. In ISO class 5 environment (PEC) draw up ½ of final vial volume of SCMC gel and transfer to sterilized, depyrogenated vial(s) (e.g. if vial volume is 5 mL add 2.5 mL of gel).
5. Filter sterilize corticotrophin solution with 0.2 micron, adding equal volume of solution to vial(s) in step 4.
6. Continue steps 4 and 5 until vials are completed.
7. Stopper vials with sterilized stoppers, seal and crimp.
8. Quality assessments
    a. Sterility
    b. Endotoxin
    c. Particulate

d. Label - auxiliary labels, storage, BUD, compounded medication

Protect from light
Store at Refrigerated

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, and 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.

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.

Although much attention has been paid to ensure the accuracy of the formulation contained here, Spectrum Pharmacy Products accepts no liability for the loss or damage arising from reliance on the information. Compounding pharmacists using this formula take full responsibility for the formulations and hold Spectrum Pharmacy Products and Spectrum Chemical Mfg Corp. and its officers, directors and employees harmless for any claim arising from use of or reliance on information contained therein.
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