Suggested Formula

Deoxycholic Acid Sodium 1% (10mg/mL) Injection Solution
Version number: 1.0
Volume: 100 mL

Deoxycholic Acid Sodium*	1 g
Sodium Chloride, USP	0.759 g
Benzyl Alcohol, NF (parenteral grade)**	0.1828 g
Water for Injection, USP	Q.S. 100 mL

*Pharmacists are advised to consult USP General Chapter <797> for ingredient selection.
**Spectrum Pharmacy Products' current material is not parenteral grade.

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. In an appropriate size vessel, dissolve Deoxycholic Acid Sodium in Water for Injection by mixing or stirring. Use an amount of Water for Injection that is approximately 90% of the final volume.
2. Add Sodium Chloride to step 1 and mix until dissolved.
3. Add Benzyl Alcohol to step 2 and mix until dispersed.
4. Bring step 3 to final volume with Water for Injection and mix well.
5. Filter step 4 through a 0.2 or 0.22 micron filter into sterile vials.
6. Suggested Quality Assessments – follow pharmacy SOPs:
    a. Bubble point filter integrity
    b. Particulate
    c. Sterility
    d. Endotoxins
    e. Label - auxiliary labels, storage, BUD, compounded medication

Protect from light
Store at Controlled Room Temperature

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.

Beyond-Use Date should be assigned based on the current USP <797> Standards

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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