

**SUGGESTED FORMULA**

Betamethasone Dipropionate 0.1% and Salicylic Acid 2% Lotion

Version number: 1.0

Volume: 100 mL

Betamethasone Dipropionate	130 mg
Salicylic Acid	2 g
Isopropyl Alcohol	40 g
Edetate Disodium Dihydrate	32 mg
Hydroxypropyl Methylcellulose (Methocel™ E4M)	550 mg
Sodium Hydroxide	550 mg
Hydrochloric Acid 37%	qs
Sodium Hydroxide 10% Aqueous Solution	qs
Water, Purified USP	qs 100 g

Notes: This formula is prepared on a w/w basis and requires pH adjustment. The isopropyl alcohol should be 99% concentration. Betamethasone Dipropionate 1.3-mg is equivalent to betamethasone 1-mg. Reference formula: CompoundingToday.com, Formula 2085.

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. Place 25 mL purified water in a beaker and slowly add the hydroxypropyl methylcellulose with vigorous mixing
4. Separately, dissolve the Betamethasone Dipropionate in 4 mL Isopropyl Alcohol; then add an additional 20 Isopropyl Alcohol to complete dissolution
5. In a separate beaker, dissolve the Sodium Hydroxide in 5 mL purified water; in another separate container, dissolve the Edetate Disodium in 5 mL purified water
6. In a separate container, dissolve the Salicylic Acid in 10 mL purified water
7. Add 20 mL of Isopropyl Alcohol to the Edetate Disodium solution mixing slowly for 15 minutes; after mixing, add to the Sodium Hydroxide solution
8. Add the mixture in Step 7 to the Salicylic Acid solution and mix vigorously; use small amounts of purified water to rinse all containers and add to the mixture
9. Adjust the pH to 4.8 to 5.3 with Citric Acid 10% solution or Sodium Hydroxide 10% solution
10. Add the solution in Step 9 to the hydrated Hydroxypropyl Methylcellulose suspension and mix well

11. If needed, bring to weight with purified water.
12. Package and label
13. Suggested quality assessments:
 - a. theoretical weight compared to actual weight
 - b. pH
 - c. color
 - d. texture-surface
 - e. appearance

Labeling should include:

- Shake well
- For external use only
- Keep away from eyes and mucous membranes
- Apply very sparingly to affected area
- Keep out of reach of children

Store in tight, light-resistant container

Store at room temperature away from excessive heat

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 is estimated to be 30 days or as directed by the current USP Chapter <795>

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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