

**SUGGESTED FORMULA****Codeine and Terpin Hydrate Elixir, Not NF**

Version number: 1.0

Volume: 100 mL

Codeine (Monohydrate)	0.200gm
Orange Oil	0.01mL
Terpin Hydrate, USP (Monohydrate) (TE110)	1.7gm
Alcohol, 190 Proof, USP (ET108)	43mL
Benzaldehyde, NF (BE128)	0.005mL
Glycerin, USP (G1016)	40mL
Syrup, NF (SY105)	10mL
Purified Water, USP	q.s. 100mL

*To obtain the quantity of orange oil and benzaldehyde, it may be necessary to prepare a dilution in alcohol; remember to subtract the quantity of alcohol used from the quantity presented in the formula. The form of Codeine, salt form and hydrated, must be taken into consideration for this preparation.

SUGGESTED COMPOUNDING PROCEDURES

1. Calculate the required quantity of each ingredient for the total amount to be prepared
2. Accurately weight and/or measure each ingredient
3. Dissolve Terpin Hydrate and codeine in the alcohol with the orange oil benzaldehyde
4. To the solution add the glycerin and syrup NF and mix well
5. Slowly, add sufficient purified water to volume and mix well
6. Package and label
7. Suggested Quality Assessments – follow pharmacy SOPs:
 - a. Color
 - b. Clarity
 - c. Aroma

*Keep away from mucus membranes

For Oral use only

*May cause drowsiness

*Shake well

Store in air tight amber plastic containers, Store at Room Temperature

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 <795> 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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