



SUGGESTED FORMULA

Tadalafil 21mg Sublingual Troche

Version number: 1.0

Volume or quantity: 30 Troches

Tadalafil (T1617)	0.63 g
Colloidal Silicon Dioxide, NF,EP (S1510)	0.30 g
Stevioside (S1964)	1.0 g
Acacia, NF (GU115)	0.50 g
Polyethylene Glycol 1450 MW, NF (P1492)	30 g

SUGGESTED COMPOUNDING PROCEDURES:

The strength of troche may range from 1 to 25mg. The quantity of PEG 1450 may need to be altered depending upon the size of the molds used. Calibrate Troche Mold and adjust formula as needed. This formula is based on approximately 1 g per troche. It is desirable to calculate for approximately 10% overage of the ingredients to adjust for excess materials required.

SUGGESTED MIXING INSTRUCTIONS:

1. Calculate the required quantity of each ingredient for the total amount to be prepared
2. Accurately weigh and/or measure each ingredient
3. Heat the PEG 1450 until melted in a beaker to about 55°C
4. Triturate the tadalafil, acacia and stevia to a fine powder in a glass mortar and pestle
5. Add the fine powder mixture to the heated PEG 1450 and mix well
6. Pour into molds and allow to cool
7. Package and Label; Refrigerate
8. Suggested Quality assessments:
 - a. color, texture, appearance
 - b. troche cavity filled / not overfilled
 - c. mixing and filling/potency studies
 - d. Label - auxiliary labels, storage, BUD, compounded medication

Store in air-tight container, Refrigerated.

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 from 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 of 6 Months per current standards of USP General Chapter <795>

Precautions:

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.

11/18 mc