SUGGESTED FORMULA

Tadalafil 10 mg Mini Troches

Version number: 1.0

Volume or quantity: 50 Troches

Tadalafil, USP	0.5 g
Colloidal Silicon Dioxide, USP	0.3 g
Acesulfame Potassium, NF	0.055 g
Acacia, NF	0.220 g
Flavor	0.12 mL*
Polyethylene Glycol 1450, NF	7 g

SUGGESTED COMPOUNDING PROCEDURES

* Teaberry or citrus oil. This formula is calculated for a 50-cavity mold, each troche weighing a total of 200mg. The density of the dosage form will be different when varying amounts of active pharmaceutical ingredients are used. Prior to beginning, it is necessary that any mold be calibrated with the formula to determine the quantity of base required. It is desirable to calculate for approximately 10% overage to adjust for the excess material required.

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh/measure each ingredient.
3. Tape one side of a 5-cavity, 200mg tablet triturate mold to clean, non-porous surface.
4. Lightly spray the top side of the mold with food-grade non stick spray.
5. Triturate tadalafil to fine powder add silica gel, acesulfame and acacia, triturate and mix until uniform.
6. Melt polyethylene glycol to 55°C.
7. Add flavor.
8. Add powders from step 5 and mix well.
9. Allow mixture to cool a few degrees and draw into a syringe.
10. Fill each cavity in mold, repeating until all cavities are filled.
11. Allow to cool.
12. Remove tape carefully and press troches from mold. Sample troche weights.
13. Package and label.
14. Suggested Quality assessments:
    a. color, texture, appearance
    b. weights
    c. mixing and filling/potency studies
    d. Label - auxiliary labels, storage, BUD, compounded medication

Store in air-tight container, at controlled 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 from reference books, peer-reviewed literature, 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 estimated to be 6 months

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 (powder-containment hoods) when weighing and mixing.

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