



SUGGESTED FORMULA

Tadalafil 5 mg Slow-Release Capsule

Version number: 1.0

Volume or quantity: 100 capsules

Tadalafil, USP (T1617)	0.5 g
Hypromellose, USP (H1128)	14.5 g
Size #3 capsules	#100

SUGGESTED COMPOUNDING PROCEDURES

Weigh all ingredients

1. Triturate to reduce to fine powders as needed
2. Mix powders per pharmacy SOPs – (e.g. geometric dilution, blade, v-blend, RAM™)
3. Fill capsules in vented enclosure (hood) per pharmacy procedure
4. Cap and “snap” each bottom into its lid.
5. Weigh sample capsules to check variability and standard deviation per pharmacy SOPs
6. Package and label with prescription label and appropriate auxiliary labels.
7. Suggested Quality assessments
 - a. % variability & % deviation from theoretical <10% - (remake if >10%)
 - b. Capsule size
 - c. Capsule color
 - d. Quantity
 - e. 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, 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 guidelines – 6 months

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.

6/18 RD