

SUGGESTED PROCEDURE

Item	Progesterone Troches (50mg)	Formula Date	07 Jul 2022
API(s)	Progesterone USP Micronized	Procedure No.	P2573
Base	Techna 10 SF™ Unsweetened Approx. Relative Density 1.2g/cm ³	Revision	R02
Volume/Quantity	30 Troches	Compound Type	Anhydrous

Rx Unflavored	30 Troches	+10% overage	Total	Percent	Comment
Techna 10 SF™ Unflavored	33.99g	3.399g	37.39g		qs
Progesterone USP Micronized	1.50g	0.150g	1.65g		API
TruClear Stevia Plus	0.18	0.018g	0.20g	0.5%	
Natural Liquid Flavor Concentrate (WS)	0.18	0.018g	0.20g	0.5%	To Taste

The above is based on an average Techna 10 SF™ calibration weight (using SmartScripps™ troche mold with cavities of 1.195g fill weight) of 36.0g (30 troches) using a 100% displacement factor for Progesterone USP Micronized.

Method of Preparation

1. Determine the total quantity to be prepared and accurately weigh/measure each of the ingredients (depending on the size of the mold to be used, the formula may need to be adjusted). Most powders are added or deleted at a displacement factor of 70%, with the exception of highly micronized powders or liquids that would have a displacement factor of 100%. It is recommended that you compound placebos to determine the average total base amount required. Note the API temperature degradation threshold.
2. Melt the Techna 10 SF™ Base to 50°C. Do not overheat at high temperatures.
3. Once Techna 10 SF™ reaches a working temperature appropriate for the active(s) used, levigate the API(s) into the melted base careful to prevent clumping, and ensuring addition is uniform before adding additional powder(s) while maintaining a good working temperature. Mix thoroughly.
4. Once the API(s) have been added, incorporate the sweetener and flavor to preference and mix well to form a homogeneous dispersion.
5. **Pour temperature of the mixture is critical for achieving a smooth surface troche. Pour temperature must be between 45-50°C. Pouring with mixture at 45°C is ideal.**
6. Pour the mixture into the SmartScripps™ Troche Molds, quickly filling each cavity.
7. Allow to cool at room temperature. **Cooling in refrigerator or freezer may result in surface deformations.** Set times will vary but should be between 10-15 minutes.

Packaging: Package in a tight, light-resistant container.

Estimated Beyond Use Date: 180 days per USP 795*

Labeling: Keep out of reach of children. Use only as directed. Protect from Heat. Store cold/refrigerated.

Stability: Anhydrous formulation. Contact SRx if stability studies have been reported for this formulation.

Note: Potency Range Recommendation: ≥90% and ≤110% of the theoretically calculated active(s).

***Beyond-Use Date should be based on the current USP General 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. 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.

WARNING! Precautions should be taken when handling and compounding hormones and other steroids, as they can be absorbed through the skin, mucus membranes and lungs if inhaled. Always wear protective lab apparel, gloves, eye protection, respirator / work under a safety cabinet.

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