

Techna 10 SF[™] Troche Base w/Bitter-Bloc Technology

Techna 10 SF is one of our proprietary troche bases that offers an improved mouthfeel, relatively quick dissolution rate, a smooth finished product surface finish with reduced Polyethylene Glycol (PEG) yet able to tolerate a relatively high API load. Techna 10 SF is sugar-free, naturally sweetened with our TruClear Stevia Plus™, includes natural suspending agents as well as other natural flavor enhancers. Techna 10 SF contains our natural bitterness blocking technology that is excellent in blocking bitter and metallic off-notes from numerous compounds such as progesterone at the oral receptor sites. Techna 10 SF Troche Base is ready for the addition of actives, flavors, and colors.

| Rx: | |
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| Techna 10 SF Troche Base | qs |
| Active Drug | qs |
| Sweetener (to preference) | qs |
| Flavor (water miscible) | qs |
| Color | qs |

- 1. Calculate the quantity of each ingredient for the total amount to be prepared.
- 2. Accurately weigh/measure each ingredient. It is recommended that you compound placebos to determine the average total base amount required. Note the API temperature degradation threshold.
- 3. Melt Techna 10 SF up to 45-55°C using an accurate heating mantle or water bath and thermometer. Do not overheat at high temperatures.
- 4. Once Techna 10 SF reaches a working temperature appropriate for the active(s) used, add API(s) into the melted base, prevent clumping, and ensuring addition is uniform before adding additional powder while maintaining a good working temperature. Mix thoroughly.
- 5. Once the API(s) have been added, add additional sweetener, flavor and color to preference and mix well.
- 6. <u>Pour temperature of the mixture is critical for achieving a smooth surface troche. Pour temperature</u> <u>must be between 45-50°C. Pouring with mixture at 45°C is ideal.</u>
- 7. Pour the mixture into the SmartScripps[™] Troche Molds, quickly filling each cavity.
- 8. Allow to cool at room temperature. <u>Cooling in refrigerator or freezer may result in surface deformations.</u> Set times will vary but should be between 10-15 minutes.

Formulas and procedure should be adjusted base on use and the variety / quantity of ingredients to be used.

Equipment Required:

- Heating mantle/water bath
- Beaker
- Stir bar
- Thermometer
- Glass stir rod
- Balance
- SmartScripps[™] Troche Molds

Storage Requirements: Can be stored at room temperature or refrigerated.

Disclaimer: SpecializedRx makes no warranties or claims to the accuracy or completeness of the above information given the variations in use and formulations.



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Technical Data Sheet

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| CATEGORY | An anhydrous, sugar-free troche base that incorporates a unique natural bitter blocking technology for use in lozenge type oral/buccal cavity preparations. Enhanced with natural sweeteners and suspending agents, it is ideally suited for buccal absorption of APIs. Additional flavors, colors, and sweeteners can be easily incorporated. To compound, heat Techna 10 SF to near 50°C until liquified while stirring. Add APIs to liquid and mix uniformly. Pour into SmartScripps Troche Mold and allow to cool to room temperature. | | |
| INGREDIENTS | A proprietary pharmaceutical grade Polyethylene Glycol blend that includes TruClear Stevia Plus™ (natural sweetener), Natural gums (natural thickening/suspending agent) and our Bitter-Bloc™ (natural bitter blocker / flavor enhancer). | | |
| ALLERGY | Per the 2004 Food Allergen Labeling and Consumer Protection Act, no allergen declarations are required for this product as relating to corn, milk, egg, tree nut, fish, crustacean shellfish, wheat, peanuts, and soybeans. Gluten-free, non-GMO/vegan compliant. | | |
| KOSHER STATUS | All ingredients are certified Kosher by the Orthodox Union (OU). | | |
| TECHNICAL DATA | Description: White to off-white granular powder Melting range: 42-46°C Shelf Life: 2 years from date of manufacture when stored in its original, unopened container. Density, g/cm ³ at 60°C approx. 1.29 | | |
| SAFETY DATA | All ingredients classified as "Generally Recognized As Safe" (GRAS) and inactive excipient ingredients by the US FDA. For information on the toxicology and safety of this product, please consult the material safety data sheet (MSDS). | | |
| HANDLING AND STORAGE | Comment: Due to some fine particles, this product is liable to become compacted or conglomerated. Storage Conditions: Product can be stored at ambient conditions for temperature, pressure, and humidity. Product should be kept in a tightly sealed container, under cool and dry conditions below melting range or refrigerated. | | |
| COMMENTS | SpecializedRx makes no warranties or claims to the accuracy or completeness of the above information given the variations in use and formulations. | | |