

Klear Gummy™ Anhydrous Base With Bitter-Bloc Technology

Klear Gummy™ is an excellent option for troches and chew type prescriptions allowing for easy compounding of water-unstable APIs, or where stability of a drug is unknown. Klear Gummy™ is a semi-transparent, mild to no taste or smell, easy to use anhydrous gelatin base derived from naturally sourced ingredients. This base has a relatively low working temperature when heated to form a pourable solution that forms a stable gelatin matrix when cooled. Excellent API load capacity. Compatible with SpecializedRx water soluble and oil soluble SRx flavors. Klear Gummy™ can be sweetened and flavored to preference.

Klear Gummy™ gives pharmacists the convenience of an anhydrous gummy base allowing for a 180-day beyond-use dating (BUD) stability profile per USP <795>. Klear Gummy™ Anhydrous is dye, gluten, sugar, PEG, paraben-free, and contains our Bitter-Bloc™ Technology for optimal palatability.

Rx:

Klear Gummy Anhydrous Base	qs
Active Drug	qs
Flavor	qs
Sweetener	qs
Color	qs

Klear Gummy™ Anhydrous 250g, Item# B0253-45
Klear Gummy™ Anhydrous 500g, Item# B0253-50
Klear Gummy™ Anhydrous 1Kg, Item# B0253-55

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 Klear Gummy up to 90°C using an accurate heating method and thermometer.
 - a. Double Boiler Method: Place small pieces in covered top pan of double boiler over hot to simmering water. Allow to melt fully with consistent stirring.
 - b. Direct Heat Method: Set hot plate to 90C. Add small pieces to beaker and cover. Stir consistently to avoid scorching. Remove from heat when lumps fully melt.
 - c. Microwave Method: Using microwave safe container, place in microwave at medium power (50%) for 20 second intervals of heating/stirring as scorching can occur, until fully melted.
4. Klear Gummy when fully melted should reach a fluid consistency. Not recommended to overheat at prolonged high temperatures. Gelatin is a thermoreversible (ability to reheat) polymer that rapidly starts to lose gel strength above 100°C (212°F) and starts degrading above 200°C (392°F).
5. Once Klear Gummy reaches a working temperature appropriate for the active(s) used, add API(s) into the melted base, or wet with glycerin to prevent clumping, and ensuring addition is uniform before adding additional powder while maintaining a good working temperature. Mix thoroughly. The base viscosity can be adjusted to preference with the addition of glycerin.
6. Once the API(s) have been added, add additional sweetener, flavor and color to preference and mix well.
7. Pour the mixture into the SmartScripps™ Troche Molds, quickly filling each cavity.
8. Allow to cool at room temperature. **Cooling in refrigerator will accelerate set times.** Set times at room temperature may vary but should be between 30-60 minutes.

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

Equipment Required:

- Hot Plate or Double Boiler or Microwave, Beaker, 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

CATEGORY	An anhydrous gummy base for use in lozenge or chew type preparations. Klear Gummy is virtually odorless, tasteless and when heated, has a slightly translucent light amber appearance. Once heated, it becomes fluid, allowing for easy incorporation of other ingredients including additional sweeteners and flavors to preference.
INGREDIENTS	A proprietary specifically formulated gelatin blend that includes Bitter-Bloc™ (Natural Flavor) technology. Ingredients are non-GMO, gluten-free, PEG-free, wheat-free, classified GRAS status, and derived from natural sources.
ALLERGY	Per the 2004 Food Allergen Labeling and Consumer Protection Act, no allergen declarations are required for this product as relating to milk, egg, tree nut, crustacean shellfish, wheat, peanuts, and soybeans.
TECHNICAL DATA	Description Shelf Life: 1 year from date of manufacture when stored in its original, unopened container. Klear Gummy Anhydrous approx. density: 1.22 g/cm ³
SAFETY DATA	All ingredients classified as “Generally Recognized As Safe” (GRAS) and inactive excipient ingredients by the US FDA.
HANDLING AND STORAGE	Comment: Protect from direct sunlight, prolonged heat, and humid conditions. Storage Conditions: Product can be stored at ambient conditions for temperature, pressure, and humidity. Product should be kept in a tightly sealed container, under dry conditions. Refrigerated conditions recommended.
COMMENTS	This information reflects US requirements for ingredients and allergy declarations. SmartScripps™ Troche Mold average Klear Gummy blank weight is approx. 1.22 g.