

Specialized Rx Products 7237 University Ave NE Fridley, MN. 55432 USA 888.512.1209 www.specializedrx.com

PolyBlend Rx™ Suppository Base

PolyBlend Rx is an anhydrous granular form pharmaceutical base used in the preparation of suppositories when a water-soluble or water-miscible base is preferred. PolyBlend Rx consists of varying molecular weight polyethylene glycols with improved emulsifiers and mold release characteristics. Due to the specific polyethylene glycols used in this proprietary blend, PolyBlend Rx exhibits excellent stability at room temperature. PolyBlend Rx releases active pharmaceutical ingredients by dissolving rather than melting, providing an extended disintegration time. Recommended for vaginal and rectal suppositories with a long history of use in pharmaceutical applications worldwide. Includes added emulsifying properties that help with dispersibility and bioavailability of hydrophobic actives. Mold lubrication not required.

Test	Specification
Appearance	White Solid
Odor	Mild to Odorless
Melting Point	50.0 to 60.0 °C
Specific Gravity	1.177 at 24 °C

Rx:

PolyBlend Rx qs Active Drug qs

- 1. Calibrate molds before use.
- 2. Calculate the quantity of each ingredient for the total amount to be prepared.
- 3. 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.
- 4. Melt PolyBlend Rx at 60-70°C.
- 5. Add API to melted PolyBlend Rx, slowly stirring until a homogenous suspension is achieved.
- 6. Quickly pour the mixture into molds. Slightly overfill to account for contraction upon cooling. Cool and dispense. Refrigerated finished product will set up in 20 minutes. Do not freeze. Recommended refrigerated storage for finished suppositories.

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 granular form base for use in suppository type preparations when a water-soluble or water-miscible extended API release base is preferred. Recommended for vaginal and rectal drug delivery suppositories. Mold lubrication is not necessary. PolyBlend Rx has excellent mold release characteristics.
INGREDIENTS	The product is a manufactured mixture of polyethylene glycols and an emulsifier.
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, fish, crustacean shellfish, wheat, peanuts, corn, and soybeans.
KOSHER	All ingredients are certified Kosher by the Orthodox Union (OU).
TECHNICAL DATA	This product is a pharmaceutical ingredient. It is recommended for use in pharmaceutical formulations administered by rectal/vaginal routes. This ingredient must be used according to appropriate regulations. PolyBlend Rx is very heat stable up to 93°C (200°F) without affecting chemical properties. Specialized Rx accepts no responsibility for the use of this product in applications other than those recommended. SOLUBILITIES AT 20°C - Water: soluble
SAFETY	For information on the toxicology and safety of this product, please consult the material safety data sheet (MSDS).
HANDLING AND STORAGE	Store the product in its original packaging sealed tightly, protected from light and moisture. Store at a temperature less than or equal to 30 °C. During storage at high temperature (> 40°C), there is a risk of agglomeration. Do not store in polystyrene containers.
COMMENTS	Specialized Rx makes no warranties or claims to the accuracy or completeness of the above information given the variations in use and formulations.