

WITEPSOL® H15

Suppository Base



WITEPSOL® H15 is an NF grade, small pastille form, hard fat suppository base comprised of glycerides from vegetable origins. It is suitable for both rectal and vaginal use and has a long history of use with a wide range of APIs. It is readily soluble in diethylether, toluene, and n-hexane and slightly soluble in anhydrous ethanol and methylene chloride. Practically insoluble in water. This base has a hydroxyl value of 5-15. It is used as a compound for suspension suppositories having a proportion of solid active compounds of less than 25%. WITEPSOL® H15 meets the requirements of USP-NF (Hard Fat) and Ph. Eur. (Hard Fat With Additives).

Test	Specifications
Appearance	Waxy Solid
Odor	Odorless
Melting Point	33.5 to 35.5°C (92.3 to 95.9°F)
Hydroxyl Value (NV=25)	5 to 15 mgKOH/g
Acid Value	<= 0.50 mgKOH/g
Peroxide Value	<= 3.0 meq O/Kg
Saponification Value	<= 230-245 mgKOH/g
Density	Average relative density at 20 °C = 0.96 g/cm3

Category	Suppository Base
Appearance	Waxy Solid
Description	WITEPSOL® H15 a semi-solid pellet base for use in hard fat suppository type preparations. Generally recommended for rectal and vaginal drug delivery suppository and ovules base.
Ingredients	Conforms to Hard Fat, USP-NF/EP. The product is a manufactured mixture of triglycerides from vegetable origins under GMP conditions.
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. Gluten-free, non-GMO/vegan compliant.
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. SpecializedRx accepts no responsibility for the use of this product in applications other than those recommended. WITEPSOL® H15 is readily soluble in diethylether, toluene and n-hexane and slightly soluble in anhydrous ethanol and methylene chloride. Practically insoluble in water.
Safety Data	For information on the toxicology and safety of this product, please consult the material safety data sheet (MSDS).
Handling & Storage	Store the product in original packaging sealed tightly, protected from light and moisture. Store at a temperature inferior or equal to 30 °C. During storage at high temperature (> 35°C), there is a risk of pellets agglomeration. Product has a shelf-life of 3 years from manufactured date under the recommended storage conditions and should not be used after its expiry date.
Comments	SpecializedRx makes no warranties or claims to the accuracy or completeness of the above information given the variations in use and formulations.