

Witepsol® H15 (NF) Suppository Base



Witepsol®H15 is an NF grade, small pastille form hard fat suppository base comprised of glycerides from vegetable origins with a long history of use with a wide range of APIs. Suitable for both rectal and vaginal use.

Solubility: Witepsol®H15 is readily soluble in diethylether, toluene and n-hexane and slightly soluble in anhydrous ethanol and methylene chloride. Practically insoluble in water.

Witepsol®H15 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%.

Meets the requirements of USP-NF (Hard Fat) and Ph. Eur. (Hard Fat With Additives)

| Test | Specification |
|------------------------|--|
| 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/cm ³ |

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Technical Data Sheet

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| CATEGORY | 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. Other uses: capsule fillings, chewing tablets, solid lipid nanoparticles processes, microencapsulation, implants. |
| 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. Specialized Rx accepts no responsibility for the use of this product in applications other than those recommended. Solubility: 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 AND STORAGE | Store the product in its 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. |