

## 7084-TACROLIMUS

### **1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.**

#### **1.1 Identification of the substance or preparation.**

Name: Tacrolimus

Bulk code: 7084

#### **1.2 Synonyms.**

No information available.

### **2. DESCRIPTION**

Appearance: Powder.

Colour: White or almost white.

### **3. COMPOSITION/INFORMATION ON COMPONENTS.**

Formula:  $C_{44}H_{69}NO_{12}$ ,  $H_2O$

CAS: 109581-93-3

Molecular weight: 822 g/mol

Chemical name: Tacrolimus monohydrate

### **4. PHYSICO-CHEMICAL DATA.**

See detailed specifications in analysis bulletin.

**Solubility:** Soluble in ethanol, acetone, chloroform and ethyl acetate. Insoluble in water.

### **5. PROPERTIES/USES.**

ACTIVE PHARMACEUTICAL INGREDIENT.

Tacrolimus is a powerful immunosuppressive macrolide derived from *Streptomyces tsukubaensis*, and acts in a similar manner to cyclosporine. It is used to prevent or reverse rejection in patients receiving organ transplants, particularly liver grafts, and has been tried in some patients with autoimmune or immune refractory disorders.

**7084-TACROLIMUS****6. DOSAGE.**

For organ transplantation and oral therapy, the initial dose could be up to 150 µg per kg twice per day.

**7. REMARKS.**

**Storage:** Store at room temperature ( $25\pm 2^{\circ}\text{C}$ ), in a cool, dry place, away from light, in a tightly closed container.

On the certificate of analysis for each batch you can check whether the batch is suitable for parenteral use or not.

**ALLERGENS:**

- **Food allergens:** In accordance with Annex II of Regulation 1169/2011, the product contains soy and its derivatives.

**8. BIBLIOGRAPHY.**

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).