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Type of document:

#### TECHNICAL DATA SHEET

 Review date:
 Version:

 13.09.2022
 4.0

# 7135-ORLISTAT

# 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

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

Name: Orlistat Bulk code: 7135

### 1.2 Synonims.

Tetrahydrolipstatin

#### 2. DESCRIPTION

Appearance: Crystalline powder. Colour: White or almost white.

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

Formula: C29H53NO5 CAS No.: 96829-58-2

Molecular weight: 495.7 g/mol

# 4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis bulletin.

Solubility: Soluble in ethanol, insoluble in water.

#### 5. PROPERTIES/USES.

### ACTIVE PHARMACEUTICAL INGREDIENT.

Orlistat is an inhibitor of gastric and pancreatic lipase that limits the absorption of fat from the diet.

It is used alongside a diet modification to control obesity.

It may also be used in overweight patients with a body mass index of 27 kg/m2 or more, if they have other risk factors.



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#### 6. DOSAGE.

Orally:

- Usually: 120 mg oral dose three times a day at mealtimes, administered immediately before or up to 1 hour after meals.

If a meal is missed or contains no fat, the dose of orlistat should be omitted. If the patient does not lose at least 5% of their body weight during the first 12 weeks of treatment, treatment should be discontinued.

### 7. REMARKS.

#### STORAGE:

Store in a tightly closed container, protected from light, in a refrigerator at a temperature set at  $5\pm3^{\circ}$ C.

### 8. BIBLIOGRAPHY.

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