Type of document:
TECHNICAL DATA SHEET
Review date: Version:
13.09.2022

## 10614-TADALAFIL

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

### 1.1 Identification of the substance or preparation.

Name:Tadalafil
Bulk code: 10614

### 1.2 Synonims.

No information available.

## 2. DESCRIPTION

Appearance: Powder.
Colour: White or almost white.

## 3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula: C22H19N3O4
CAS No.: 171596-29-5
EINECS: 87-782-2
Molecular weight: $389.40 \mathrm{~g} / \mathrm{mol}$

## 4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis bulletin.

Solubility: Practically insoluble in water, slightly soluble in dimethyl sulphoxide, slightly soluble in methylene chloride.

Melting point: No information available.

## 5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

Tadalafil is a phosphodiesterase type 5 inhibitor with actions and uses similar to those of sildenafil. It is used to treat erectile dysfunction and pulmonary arterial hypertension.

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## 6. DOSAGE.

Orally:

- Erectile dysfunction: usually 10 mg at least 30 minutes before sexual activity and may be taken with or without food. The dose may be increased to 20 mg or decreased to 5 mg , if necessary. Efficacy may persist for up to 36 hours after dosing. Tadalafil should not be taken more than once every 24 hours.
- Pulmonary arterial hypertension: 40 mg once a day.


## 7. REMARKS.

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

## 8. BIBLIOGRAPHY.

"Martindale. The Extra Pharmacopoeia". 37th Edition. Ed. The Pharmaceutical Press. London. (2011).

