



GUINAMA. Laboratory distributing raw materials for the pharmaceutical and cosmetics industries.

Type of Document:

TECHNICAL DATA SHEET

Review date:

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Version:

5.0

8548-SILDENAFIL CITRATE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1 Identification of the substance or preparation

Name: Sildenafil citrate

Bulk code: 8548

1.2 Synonyms

Sildenafil citrate

2. DESCRIPTION

Appearance: Crystalline powder.

Colour: White, almost white.

3. COMPOSITION/INFORMATION ON COMPONENTS

Formula: $C_{22}H_{30}N_6O_4S \cdot C_6H_8O_7$

CAS: 171599-83-0

Molecular weight: 666.71 g/mol

4. PHYSICO-CHEMICAL DATA

See detailed specifications in the certificate of analysis.

Solubility: Slightly soluble in water and methanol. Practically insoluble in hexane.

5. PROPERTIES/USES

ACTIVE PHARMACEUTICAL INGREDIENT

14 mg of sildenafil citrate is equivalent to 10 mg of sildenafil.

It is a phosphodiesterase type 5 inhibitor.

Sildenafil is administered orally to improve the exercise capacity in pulmonary arterial hypertension. It is also used to treat erectile dysfunction.



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6. DOSAGE

In cases of pulmonary arterial hypertension, it is administered orally in a dose of 20 mg three times a day. In cases of erectile dysfunction, the usual dose is equivalent to 50 mg of sildenafil, approximately 1 hour before sexual intercourse. The dose can be increased or decreased depending on the response. The maximum recommended dose is 100 mg and sildenafil should not be consumed more frequently than one dose every 24 hours.

An initial dose that does not exceed 25 mg/day is recommended in patients treated simultaneously with sildenafil and cytochrome P450 3A4 isoenzyme inhibitors.

7. REMARKS

STORAGE:

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

Slightly hygroscopic.

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

8. BIBLIOGRAPHY

"Martindale. 2013, Pharma Editores, S.L.