91151-DILTIAZEM HCL

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1 Identification of the substance or preparation

Name: Diltiazem HCL
Bulk code: 91151

1.2 Synonyms

Diltiazemi hidrochloridum; Latiazem hydrochloride; Diltiazem hydrochloride.

2. DESCRIPTION

Appearance: Crystalline powder or small crystals.
Colour: White
Smell: Odourless
Flavour: Bitter

3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula: $C_{22}H_{26}N_2O_4S$, HCl
CAS: 33286-22-5
Molecular weight: 451.0

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis report.

Solubility: Highly soluble in water, chloroform, formic acid and methanol; barely soluble in absolute alcohol. Practically insoluble in ether and benzene.

Melting point: Approximately 213ºC with decomposition.

5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

It is a blocking agent for the slow calcium channels, pertaining to the group of benzodiazepines. It acts by inhibiting the contractile process of the vascular smooth muscle, which translates into arteriolar vasodilation with a reduction in peripheral resistance. With regard to coronary circulation, it causes general dilation, which determines an increase in blood flow and, consequently, myocardial oxygenation. In terms of the cardiac muscle, it reduces contractility and inhibits and delays cardiac conduction.
Its vasodilation properties are less pronounced than those of nifedipine. In addition, it is used as a class 4 antiarrhythmic, antihypertensive, anti-anginal and peripheral vasodilator.

It is administered orally when treating angina pectoris, as well as (either alone or in combination) in cases of high blood pressure and heart attack, with doubtful results.

6. DOSAGE.

The starting oral doses for angina pectoris are usually 60 mg, three times a day, and are increased if necessary at intervals of 1-2 days. Individual requirements vary considerably as some patients need 360 mg/day, while others require up to 480 mg, in sustained release tablets in cases of unstable angina.

In high blood pressure, starting doses are 60-120 mg, twice a day, in sustained release tablets or capsules, increasing in 14-day intervals according to personal needs, up to a maximum of 360 mg/day.

In elderly people or patients with kidney or liver function problems, doses must be reduced.

These doses should not be increased when the heart rate is under 50 beats per minute.

7. REMARKS.

STORAGE:

Store at room temperature (25±2ºC), in a cool, dry place, away from sunlight, in a hermetically sealed container.

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

8. BIBLIOGRAPHY.

Pharmaceutical Monographs. COF Alicante, 1998.

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