



LUSOCHIMICA

COPIA CONFORME ALL'ORIGINALE
COPY CONFORMS TO THE ORIGINAL
X QUALITY CONTROL MANAGER

FR 05102118

CERTIFICATE OF ANALYSIS

Certificate N.: 290/18

Issue n° 15 of 09/01/2017

Product: **DILTIAZEM HYDROCHLORIDE**

Batch: **DIL 518**

Batch size: 618.700 kg

Conforms to: Ph. Eur. 9th ed. - Lusochimica specifications Issue N° 19 of January 09, 2017; effective from: 11/01/2017
Code: 25

Manufacturing date: March 2018

Retest date: March 2023

DESCRIPTION AND SOLUBILITY

White or almost white crystalline powder.

Freely soluble in water, in methanol and in methylene chloride, slightly soluble in ethanol 99.5%.

TESTS	RESULTS	SPECIFICATIONS
Description	corresponds	corresponding
Identification		
- IR	corresponds	corresponding
- Chloride reaction	positive	positive
Melting point	210°C - 211°C	about 213°C with decomposition
Appearance of solution		
- Clarity	clear	clear
- Colour	colourless	colourless
pH	5.1	4.3 to 5.3
Specific optical rotation	+ 117°	+ 115° to + 120°
Related substances:		
- Impurity F	less than 0.05% (DL)	not more than 0.3%
- Impurity E	less than 0.05% (DL)	not more than 0.10%
- Each unknown impurity	less than 0.05% (DL)	not more than 0.10%
- Total of related substances	less than 0.05% (DL)	not more than 0.3%
Loss on drying	0.1%	not more than 0.5%
Sulphated ash	less than 0.1%	not more than 0.1%
Assay (on dried substances), - potentiometric	99.7%	98.5% to 101.0%

ADDITIONAL TESTS:

Heavy metals	less than 10 ppm	not more than 10 ppm
Residual solvents (HS-GLC)		
- Butanol	476 ppm	not more than 1000 ppm
- Acetone	54 ppm	not more than 300 ppm
- Toluene	1 ppm	not more than 50 ppm
- N,N-dimethylformamide	less than 90 ppm (DL)	not more than 800 ppm

Residual solvent content complies to current USP <467> and ICH Q3C.

MANUFACTURING SITE: Lusochimica S.p.A. Lomagna (LC) ITALY

NOTES: store in tight, light-resistant container.

APPROVED BY Q.C. MANAGER

Date 16/05/2018

I declare that the product is manufactured in accordance with the guidelines on Good Manufacturing Practice for Active substances.

RELEASED BY Q.P.

Release date:

17/05/18

ATRICION 4022. Noche en caso de emergencia. En caso de emergencia, contactar con el Centro de Información Toxicológica (CIT) al teléfono 011 222 222 222. El CIT es un servicio de atención al cliente que proporciona información sobre los productos farmacéuticos y los productos químicos. El CIT es un servicio de atención al cliente que proporciona información sobre los productos farmacéuticos y los productos químicos.

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DILTIAZEM CLH. GRANEL

Fecha Entrada: 21-02-2019

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