

**LUSOCHIMICA** S.p.A.COPIA CONFORME ALL'ORIGINALE
COPY CONFORMS TO THE ORIGINAL
QUALITY CONTROL MANAGER*R. B.* 21/02/2011**CERTIFICATE OF ANALYSIS**

Certificate N.: 296/10

Issue n° 7

Product: **DILTIAZEM HYDROCHLORIDE**Batch: **DIL 910** ✓Conforms to: Ph Eur Supplement 6.8 to the 6th ed. - Lusochimica specifications Issue N° 11 of July 01, 2010
Code: 25

Manufacturing date: May 2010

Retest date: May 2015

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
Solubility	corresponds	corresponding
Identification		
- IR	corresponds	corresponding
- Test of chloride	positive	positive
Melting point	212°C - 213°C with decomposition	About 213°C with decomposition
Appearance of solution		
- Clarity	clear	clear
- Colour	colourless	colourless
pH	4.8	4.3 to 5.3
Specific optical rotation	+ 116°	+ 115° to + 120°
Related substances:		
- Desacetyl Diltiazem Hydrochloride	0.06%	not more than 0.10%
- Thiazepinone	less than 0.05% (disregard limit)	not more than 0.10%
- Each unknown impurity	less than 0.05% (disregard limit)	not more than 0.10%
- Total of related substances	0.1%	not more than 0.3%
Heavy metals	less than 10 ppm	not more than 10 ppm
Loss on drying	0.1%	not more than 0.5%
Sulphated ash	less than 0.1%	not more than 0.1%
Assay	100.4%	98.5% to 101.0%

ADDITIONAL TESTS:

Residual solvents (HS-GLC)		
- Butyl alcohol	437 ppm	not more than 1000 ppm
- Acetone	39 ppm	not more than 300 ppm
- Toluene	less than 0.5 ppm (DL)	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 *Ricardo B.*

Date 02/08/2010

RELEASED BY Q.P. *Giuseppe Ungolini*

Release date: 25/08/2010

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