

Lote: 0041212

LUSOCHIMICA S.p.A.

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

16/11/2012

CERTIFICATE OF ANALYSIS

Certificate N.: 274/12

Issue n° 9

Product: DILTIAZEM HYDROCHLORIDE

Batch: DIL 212

Conforms to: Ph. Eur. Supplement 7.4 to the 7th ed. - Lusochimica specifications Issue N° 13 of March 14, 2012
Code: 25

Manufacturing date: April 2012

Retest date: April 2017

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
- Chloride reaction	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	5.1	4.3 to 5.3
Specific optical rotation	+115°	+ 115° to + 120°
Related substances:		
- Impurity F	0.1%	not more than 0.2%
- Impurity E	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	less than 0.1%	not more than 0.5%
Sulphated ash	less than 0.1%	not more than 0.1%
Assay	100.3%	98.5% to 101.0%
ADDITIONAL TESTS:		
Residual solvents (HS-GLC)		
- Butyl alcohol	836 ppm	not more than 1000 ppm
- Acetone	265 ppm	not more than 300 ppm
- Toluene	less than 1.6 ppm (QL)	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 <i>Riccardo Borromeo</i>	Date 28/10/2012	
RELEASED BY Q.P. <i>Giuseppe Mucelli</i>	Release date: 29/10/2012	

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