

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl		COMPENDIA : Ph.Eur.-8.0
BATCH/NO. : DIL/M-02015		QUANTITY : 50 Kg
MFG. DATE : DECEMBER.2014		EXP. DATE : NOVEMBER.2019
QC A.R. No.: FP/027/2015		
TESTS	RESULTS	SPECIFICATIONS
01. CHARACTERS		
i. Appearance	White, crystalline powder.	White or almost white, crystalline powder.
ii. Solubility	Freely soluble in water, in methanol and in methylene chloride, slightly soluble in anhydrous ethanol.	Freely soluble in water, in methanol and in methylene chloride, slightly soluble in anhydrous ethanol.
iii. Melting point	Melts at 213°C with decomposition.	Melts at about 213° C with decomposition.
02. IDENTIFICATION		
IR Absorption	Concordant with working standard	IR Absorption spectrum of the sample concordant with that of the Diltiazem hydrochloride CRS / working standard.
CHLORIDES	Positive	It gives reaction to chlorides.
03. APPEARANCE OF SOLUTION		
04. pH	4.8	4.3 to 5.3
05. SPECIFIC OPTICAL ROTATION	+117°	+ 115° to + 120°
06. RELATED SUBSTANCES (By HPLC)		
Impurity F	Not Quantified	Not more than 0.3% w/w
Unspecified Impurities	Not Quantified	Not more than 0.10% w/w each
Total Impurities	Not Quantified	Not more than 0.30% w/w
07. HEAVY METALS		
08. LOSS ON DRYING	0.23%	Not more than 0.50% w/w
09. SULPHATED ASH	0.05%	Not more than 0.10% w/w
10. ASSAY (By Titration) (On dried basis)	100.17%	Not less than 98.50% w/w and Not more than 101.00% w/w
ADDITIONAL TESTS:		
1. RESIDUAL SOLVENTS:		
Toluene	309 ppm	Not more than 750 ppm
Methanol	262 ppm	Not more than 500 ppm
Isopropyl Alcohol	8 ppm	Not more than 1000 ppm
Ethyl Acetate	1 ppm	Not more than 2500 ppm

REMARKS: The product conforms to **Ph.Eur.-8.0** Specifications

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