

## **CERTIFICATE OF ANALYSIS**

PRODUCT : DILTIAZEM HCI		COMPENDIA	: Ph.Eur7.7
(MICRONISED)			1
BATCH NO. : DIL/M-10314		QUANTITY	: 500 Kg
MFG. DATE: MAY.2014		EXP. DATE	: APRIL.2019
QC A.R. No.: FP/125/2014			
TESTS		RESULTS	SPECIFICATIONS
01. CHARACTERS			
i. Appearance	A 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	Melted at 212°C with decomposition.		Melts at about 213° C with decomposition.
02. IDENTIFICATION			
IR Absorption	Concordant with working standard		IR Absorption spectrum of the sample is concordant with that of the Diltiazem hydrochloride CRS / working standard.
CHLORIDES	Positive		It gives reaction to chlorides.
03. APPEARANCE OF SOLUTION	Clear and colourless		Clear and colourless.
04. pH	4.9		4.3 to 5.3
05. SPECIFIC OPTICAL ROTATION +118°		+ 115° to + 120°	
06. RELATED SUBSTANCES	Not Quantified		Not more than 0.3% w/w
i. Impurity F ii. Unspecified Impurities	Not Quar		Not more than 0.10% w/w each
iii.Total Impurities	Not Quai		Not more than 0.30% w/w
07. HEAVY METALS		n 10 ppm	Not more than 10 ppm
08. LOSS ON DRYING	0.20%	······································	Not more than 0.50% w/w
09. SULPHATED ASH	0.01%		Not more than 0.10% w/w
10. ASSAY (By Titration)	100.35%		Not less than 98.50% w/w and
(On dried basis)	100.0070		Not more than 101.00% w/w
ADDITIONAL TEST: PARTICLE SIZE			
100%	26 Micro	ns	100% Less than 100 Microns
Surface Area	2.04 m <sup>2</sup> /gm		For Information
RESIDUAL SOLVENTS (BY GC-HS)			
Toluene	424 ppm		Not more than 750 ppm
Methanol	197 ppm		Not more than 500 ppm
Isopropyl Alcohol	Not detected		Not more than 1000 ppm
Ethyl Acetate	5 ppm		Not more than 2500 ppm
Bulk Density	0.27 g/m		For Information
Tapped Density  REMARKS: The product conforms	0.51 g/m		For Information

REMARKS: The product conforms to Ph.Eur.-7.7 & Customer's Specifications

Prepared by Executive-QC

Checked by Manager-QC Approved by General Manager-QC

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