

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)		COMPENDIA : Ph.Eur.-8.0
BATCH NO. : DIL/M-01815		QUANTITY : 500 Kg
MFG. DATE : JANUARY.2015		EXP. DATE : DECEMBER.2019
QC A.R. No.: FP/025/2015		
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	Melted 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 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	+119°	+ 115° to + 120°
06. RELATED SUBSTANCES		
i. Impurity F	Not Quantified	Not more than 0.3% w/w
ii. Unspecified Impurities	Not Quantified	Not more than 0.10% w/w each
iii. Total Impurities	Not Quantified	Not more than 0.30% w/w
07. HEAVY METALS	Less than 10 ppm	Not more than 10 ppm
08. LOSS ON DRYING	0.21%	Not more than 0.50% w/w
09. SULPHATED ASH	0.03%	Not more than 0.10% w/w
10. ASSAY (By Titration)	100.09%	Not less than 98.50% w/w and Not more than 101.00% w/w
(On dried basis)		
ADDITIONAL TEST:		
PARTICLE SIZE		
100%	35 Microns	100% Less than 100 Microns
Surface Area	1.88 m ² /gm	For Information
RESIDUAL SOLVENTS (BY GC-HS)		
Toluene	247 ppm	Not more than 750 ppm
Methanol	148 ppm	Not more than 500 ppm
Isopropyl Alcohol	11 ppm	Not more than 1000 ppm
Ethyl Acetate	2 ppm	Not more than 500 ppm
Bulk Density	0.28 g/ml	For Information
Tapped Density	0.49 g/ml	For Information

REMARKS: The product conforms to **Ph.Eur.-8.0 & Customer's Specifications**

Sealed
Prepared by
Executive-QC

Amey
Checked by
Manager-QC

Amey
Approved by
Manager-QC

Piramal Enterprises Limited

Factory: Digwal Village Kohir Mandal Medak Dist 502321 Andhra Pradesh India

T +91 8451 287508 F +91 8451 287553

Admin. Off: 5-9-30 Road # 4 Basheerbagh Palace Colony Basheerbagh Hyderabad 500 063 India

T +91 40 2322 6719 F +91 40 2326 6041 / 82

Registered Office: Piramal Tower Peninsula Corporate Park Ganpatrao Kadam Marg Lower Parel Mumbai 400 013

T +91 22 3046 6666 F +91 22 2493 6708

W www.piramalhealthcare.com