

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HC	COMPENDIA : Ph.Eur.-8.0
BATCH No. : DIL/M-21816	BATCH QUANTITY : 500.00 Kg
MFG. DATE : MAY.2016	EXP. DATE : APRIL.2021
APPROVED ON : 09/06/16	DISPATCH QUANTITY : 50.00Kg
QC A.R. No.: FP/136/2016	
TESTS	RESULTS
SPECIFICATIONS	

1. 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.
2. IDENTIFICATION		
IR Absorption	Concordant with working standard	IR Absorption spectrum of the sample concordant with that of the Diltiazem hydrochloride CRS / working standard. It gives reaction to chlorides.
CHLORIDES	Positive	
3. APPEARANCE OF SOLUTION	Clear and colorless	Clear and colourless.
4. pH	4.0	4.3 to 5.3
5. SPECIFIC OPTICAL ROTATION	+117°	+ 115° to + 120°
6. RFI ATFN 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
7. HEAVY METALS	Less than 10 ppm	Not more than 10 ppm
8. LOSS ON DRYING	0.20%	Not more than 0.50% w/w
9. SULPHATED ASH	0.02%	Not more than 0.10% w/w
10. ASSAY (By Titration) (On dried basis)	99.52%	Not less than 98.50% w/w and Not more than 101.00% w/w
ADDITIONAL TESTS:		
1. RESIDUAL SOLVENTS:		
Toluene	366 ppm	Not more than 750 ppm
Methanol	254 ppm	Not more than 500 ppm
Isopropyl Alcohol	0 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

MR 10/06/16
Prepared by Sign & Date
Executive-QC

10/06/16
Checked by Sign & Date
Manager-QC

10/06/16
Approved by Sign & Date
General Manager-QC

Piramal Enterprises Limited.

Factory : Sy.Nos 7-70,70/1 & 70/2, Digwal Village, Kohir Mandal, Medak District, Telangana, India, Pin Code: 502321

T+91 8451 287508, 287557,287558,287532 F+91 8451 287553.

Admin. Off: 5-9-30 Road # 4 Basheerbagh Palace Colony Basheerabagh 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

FAGRON IBÉRICA, S.A.U
Corresponde a lote de Fagron:

166 70-103

[Signature]
Director Técnico