

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)		COMPENDIA : Ph.Eur.-7.7
BATCH NO. : DIL/M-08614		QUANTITY : 500 Kg
MFG. DATE : APRIL.2014		EXP. DATE : MARCH.2019
QC A.R. No.: FP/103/2014		
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 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 colorless	Clear and colourless.
04. pH	4.8	4.3 to 5.3
05. SPECIFIC OPTICAL ROTATION	+117°	+ 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	0.32%	Not more than 0.50% w/w
09. SULPHATED ASH	0.02%	Not more than 0.10% w/w
10. ASSAY (By Titration) (On dried basis)	100.77%	Not less than 98.50% w/w and Not more than 101.00% w/w
ADDITIONAL TEST:		
PARTICLE SIZE		
100%	26 Microns	100% Less than 100 Microns
Surface Area	1.86 m ² /gm	For Information
RESIDUAL SOLVENTS (BY GC-HS)		
Toluene	245 ppm	Not more than 750 ppm
Methanol	239 ppm	Not more than 500 ppm
Isopropyl Alcohol	4 ppm	Not more than 1000 ppm
Ethyl Acetate	13 ppm	Not more than 2500 ppm
Bulk Density	0.25 g/ml	For Information
Tapped Density	0.48 g/ml	For Information

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

Deebu
Prepared by
Executive-QC

Lynan
Checked by
Manager-QC :

BS Jan
Approved by
General 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

PIRAMAL ENTERPRISES LIMITED

Result Analysis Report

Sample Name:
DILTIAZEM HCL

Sample Source & type:
Factory = PHL

Sample bulk lot ref:
DIL/M-08614(FP/103/2014)

SOP Name:
DILTIAZEM HCL

Measured by:
PHANI

Result Source:
Measurement

Measured:
25 April 2014 PM 02:48:39

Analysed:
25 April 2014 PM 02:48:40

Particle Name:
DILTIAZEM HCL

Particle RI:
1.500

Dispersant Name:

Accessory Name:
Scirocco 2000

Absorption:
0.001

Dispersant RI:
1.000

Analysis model:
General purpose

Size range:
0.020 to 2000.000 um

Weighted Residual:
1.031 %

Sensitivity:
Normal

Obscuration:
7.37 %

Result Emulation:
Off

Concentration:
0.0007 %Vol

Span :
2.108

Uniformity:
0.648

Result units:
Volume

Specific Surface Area:
1.86 m²/g

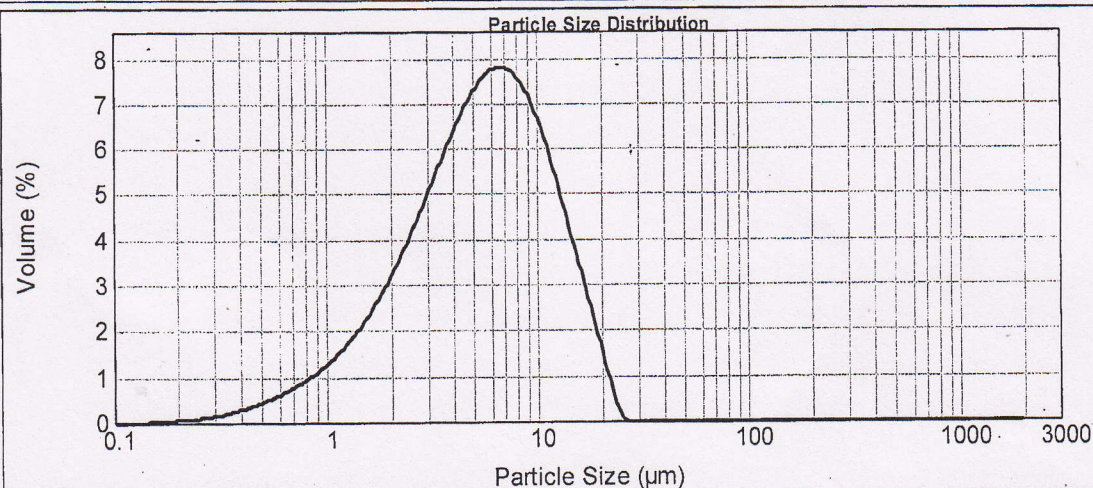
Surface Weighted Mean D[3,2]:
3.234 um

Vol. Weighted Mean D[4,3]:
6.550 um

d(0.1): 1.590 um

d(0.5): 5.484 um

d(0.9): 13.151 um



—DILTIAZEM HCL, 25 April 2014 PM 02:48:39

Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %
0.010	0.00	0.120	0.00	1.259	6.91	12.824	89.19	125.124	100.00	1258.925	100.00
0.011	0.00	0.138	0.00	1.660	10.68	14.000	91.88	142.650	100.00	1445.440	100.00
0.015	0.00	0.158	0.01	1.905	13.14	15.136	93.95	158.489	100.00	1659.587	100.00
0.017	0.00	0.182	0.03	2.188	16.06	17.378	96.88	181.970	100.00	1905.461	100.00
0.020	0.00	0.209	0.06	2.512	19.50	19.953	98.84	208.930	100.00	2187.762	100.00
0.023	0.00	0.240	0.12	2.884	23.52	22.909	99.84	239.883	100.00	2511.886	100.00
0.026	0.00	0.275	0.20	3.311	28.15	26.303	100.00	275.423	100.00	2884.032	100.00
0.030	0.00	0.316	0.31	3.802	33.40	30.200	100.00	316.228	100.00	3311.311	100.00
0.035	0.00	0.363	0.47	4.365	39.25	34.674	100.00	363.078	100.00	3801.894	100.00
0.040	0.00	0.417	0.69	5.012	45.63	39.811	100.00	416.869	100.00	4365.158	100.00
0.046	0.00	0.479	1.00	5.754	52.40	45.709	100.00	478.630	100.00	5011.872	100.00
0.052	0.00	0.550	1.40	6.607	59.40	52.481	100.00	549.541	100.00	5754.399	100.00
0.060	0.00	0.631	1.91	6.950	61.98	60.256	100.00	630.957	100.00	6606.934	100.00
0.069	0.00	0.724	2.56	8.125	69.85	69.183	100.00	724.436	100.00	7585.776	100.00
0.079	0.00	0.832	3.35	9.011	74.84	79.433	100.00	831.764	100.00	8709.636	100.00
0.091	0.00	0.955	4.31	10.000	79.58	85.124	100.00	954.993	100.00	10000.000	100.00
0.105	0.00	1.096	5.49	11.482	85.25	99.000	100.00	1096.478	100.00		

Analysed by:

25/04/14

Checked by:

MR
22/04/14