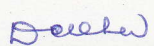


CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)		COMPENDIA : Ph.Eur.-7.7
BATCH NO. : DIL/M-08314		QUANTITY : 500 Kg
MFG. DATE : MARCH.2014		EXP. DATE : FEBRUARY.2019
QC A.R. No.: FP/099/2014		
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 colourless	Clear and colourless.
04. pH	4.9	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	0.24%	Not more than 0.50% w/w
09. SULPHATED ASH	0.03%	Not more than 0.10% w/w
10. ASSAY (By Titration)	100.68%	Not less than 98.50% w/w and Not more than 101.00% w/w
(On dried basis)		
ADDITIONAL TEST:		
PARTICLE SIZE		
100%	26 Microns	100% Less than 100 Microns
Surface Area	1.73 m ² /gm	For Information
RESIDUAL SOLVENTS (BY GC-HS)		
Toluene	252 ppm	Not more than 750 ppm
Methanol	211 ppm	Not more than 500 ppm
Isopropyl Alcohol	Not detected	Not more than 1000 ppm
Ethyl Acetate	13 ppm	Not more than 2500 ppm
Bulk Density	0.28 g/ml	For Information
Tapped Density	0.50 g/ml	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

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

IRAMAL ENTERPRISES LIMITED

Result Analysis Report

Name:
ZEM HCL
Sample Source & type:
Factory = PHL
Sample bulk lot ref:
DIL/M-08314(FP/099/2014)

SOP Name:
DILTIAZEM HCL

Measured by:
PHANI

Result Source:
Measurement

Measured:
25 April 2014 PM 02:37:22

Analysed:
25 April 2014 PM 02:37:23

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 μm

Weighted Residual:
0.739 %

Sensitivity:
Normal

Obscuration:
6.30 %

Result Emulation:
Off

Concentration:
0.0006 %Vol

Span :
2.160

Uniformity:
0.663

Result units:
Volume

Specific Surface Area:
1.73 m^2/g

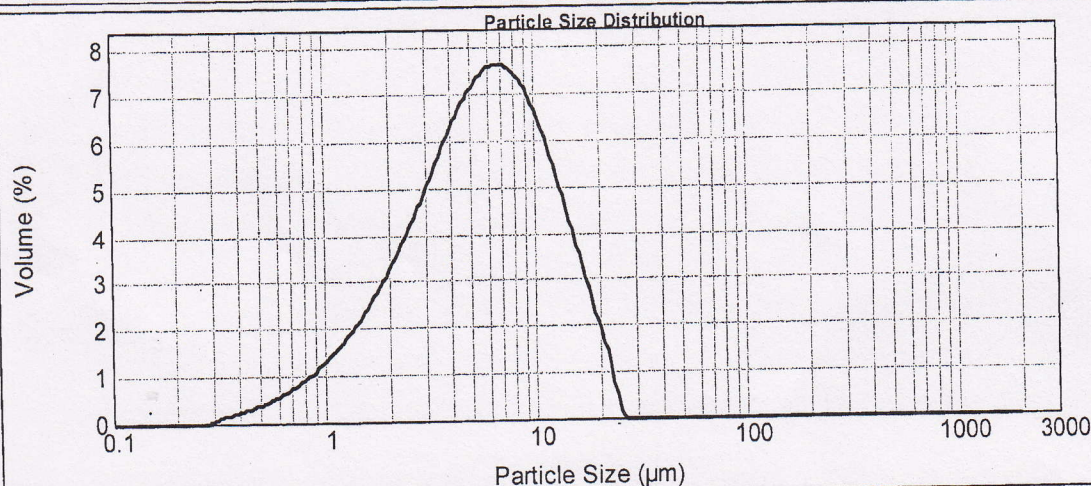
Surface Weighted Mean D[3,2]:
3.476 μm

Vol. Weighted Mean D[4,3]:
6.758 μm

d(0.1): 1.645 μm

d(0.5): 5.582 μm

d(0.9): 13.706 μm



DILTIAZEM HCL, 25 April 2014 PM 02:37:22

Size (μm)	Vol Under %
0.010	0.00
0.011	0.00
0.015	0.00
0.017	0.00
0.020	0.00
0.023	0.00
0.026	0.00
0.030	0.00
0.035	0.00
0.040	0.00
0.046	0.00
0.052	0.00
0.060	0.00
0.069	0.00
0.079	0.00
0.091	0.00
0.105	0.00

Size (μm)	Vol Under %
0.120	0.00
0.138	0.00
0.158	0.00
0.182	0.00
0.209	0.00
0.240	0.00
0.275	0.00
0.316	0.01
0.363	0.13
0.417	0.31
0.479	0.56
0.550	0.91
0.631	1.36
0.724	1.96
0.832	2.71
0.955	3.66
1.096	4.84

Size (μm)	Vol Under %
1.259	6.29
1.660	10.14
1.905	12.65
2.188	15.62
2.512	19.09
2.884	23.11
3.311	27.71
3.802	32.90
4.365	38.64
5.012	44.87
5.754	51.48
6.607	58.31
6.950	60.84
8.125	68.55
9.011	73.47
10.000	78.17
11.482	83.85

Size (μm)	Vol Under %
12.824	87.86
14.000	90.64
15.136	92.81
17.378	95.98
19.953	98.22
22.909	99.67
26.303	100.00
30.200	100.00
34.674	100.00
39.811	100.00
45.709	100.00
52.481	100.00
60.256	100.00
69.183	100.00
79.433	100.00
85.124	100.00
99.000	100.00

Size (μm)	Vol Under %
125.124	100.00
142.650	100.00
158.489	100.00
181.970	100.00
208.930	100.00
239.883	100.00
275.423	100.00
316.228	100.00
363.078	100.00
416.869	100.00
476.630	100.00
549.541	100.00
630.957	100.00
724.436	100.00
831.764	100.00
954.993	100.00
1096.478	100.00

Size (μm)	Vol Under %
1258.925	100.00
1445.440	100.00
1659.587	100.00
1905.461	100.00
2187.762	100.00
2511.886	100.00
2884.032	100.00
3311.311	100.00
3801.894	100.00
4365.158	100.00
5011.872	100.00
5754.399	100.00
6606.934	100.00
7585.776	100.00
8709.636	100.00
10000.000	100.00

Analysed by:

25/04/14

Checked by:

27/04/14