

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)		COMPENDIA : Ph.Eur.-8.0
BATCH NO. : DIL/M-17214		QUANTITY : 500 Kg
MFG. DATE : JULY.2014		EXP. DATE : JUNE.2019
QC A.R. No.: FP/211/2014		
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	+118°	+ 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	0.17%	Not more than 0.50% w/w
09. SULPHATED ASH	0.03%	Not more than 0.10% w/w
10. ASSAY (By Titration) (On dried basis)	100.12%	Not less than 98.50% w/w and Not more than 101.00% w/w
ADDITIONAL TEST:		
PARTICLE SIZE		
100%	70 Microns	100% Less than 100 Microns
Surface Area	1.6 m ² /gm	For Information
RESIDUAL SOLVENTS (BY GC-HS)		
Toluene	167 ppm	Not more than 750 ppm
Methanol	65 ppm	Not more than 500 ppm
Isopropyl Alcohol	0 ppm	Not more than 1000 ppm
Ethyl Acetate	0 ppm	Not more than 2500 ppm
Bulk Density	0.27 g/ml	For Information
Tapped Density	0.50 g/ml	For Information

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

Prepared by
Executive-QC

Checked by
Manager-QC

Approved by
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PIRAMAL ENTERPRISES LIMITED

Result Analysis Report

Sample Name:
DILTIAZEM HCL
Sample Source & type:
Factory = PHL
Sample bulk lot ref:
DIL/M-17214(fp-211-2014)

SOP Name:
DILTIAZEM HCL
Measured by:
MAHESH
Result Source:
Measurement

Measured:
29 September 2014 PM 02:38:23
Analysed:
29 September 2014 PM 02:38:25

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:
0.306 %
Sensitivity:
Normal
Obscuration:
6.12 %
Result Emulation:
Off

Concentration:
0.0006 %Vol

Span :
2.487

Uniformity:
0.811

Result units:
Volume

Specific Surface Area:
1.6 to m²/g

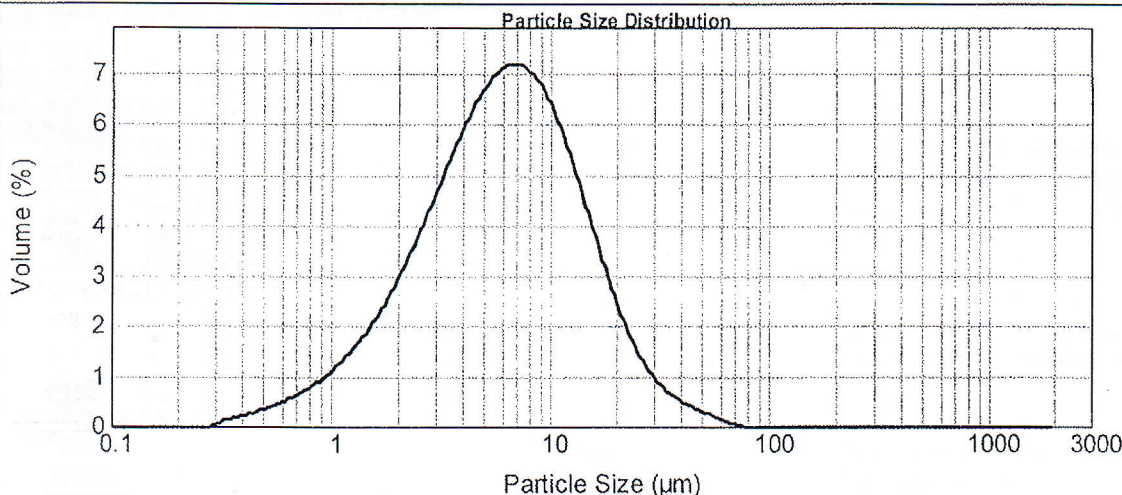
Surface Weighted Mean D[3,2]:
3.747 um

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

Samr
DIL/M-
d(0.1): 1.773 um

d(0.5): 6.086 um

d(0.9): 16.906 um



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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	1.259	5.57	8.640	66.31	26.303	96.73	174.000	100.00	1659.587	100.00
0.011	0.00	1.660	8.98	9.411	70.10	34.674	98.52	181.970	100.00	1905.461	100.00
0.017	0.00	1.905	11.23	9.900	72.27	39.005	98.98	208.930	100.00	2187.762	100.00
0.020	0.00	2.188	13.92	10.000	72.70	43.452	99.32	239.883	100.00	2511.886	100.00
0.026	0.00	2.512	17.11	10.400	74.32	70.481	100.00	275.423	100.00	2884.032	100.00
0.158	0.00	2.884	20.83	11.682	78.86	79.433	100.00	316.228	100.00	3311.311	100.00
0.275	0.00	3.311	25.11	12.452	81.16	85.000	100.00	363.078	100.00	3801.894	100.00
0.316	0.01	3.802	29.96	12.600	81.57	99.000	100.00	416.869	100.00	4365.158	100.00
0.363	0.13	4.365	35.34	13.605	84.10	99.850	100.00	478.630	100.00	5011.872	100.00
0.417	0.31	5.012	41.20	13.800	84.55	100.000	100.00	549.541	100.00	5754.899	100.00
0.479	0.55	5.754	47.41	14.490	86.01	125.000	100.00	630.957	100.00	6606.934	100.00
0.550	0.87	6.425	52.53	15.000	86.99	125.011	100.00	724.436	100.00	7585.776	100.00
0.631	1.29	7.170	57.69	15.400	87.70	126.251	100.00	831.764	100.00	10000.000	100.00
0.724	1.81	7.390	59.11	15.790	88.35	142.650	100.00	954.993	100.00		
0.832	2.48	7.458	59.54	16.308	89.15	149.400	100.00	1096.478	100.00		
0.955	3.30	7.950	62.51	17.950	91.30	150.011	100.00	1258.925	100.00		
1.095	4.32	8.020	62.91	22.909	95.26	160.000	100.00	1445.440	100.00		

Analysed by: K 29/09/14

Checked by:

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30/09/14