

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)		COMPENDIA : Ph.Eur.-8.0
BATCH NO. : DIL/M-01315		QUANTITY : 500 Kg
MFG. DATE : JANUARY.2015		EXP. DATE : DECEMBER.2019
QC A.R. No.: FP/020/2015		
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	4.7	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	0.22%	Not more than 0.50% w/w
09. SULPHATED ASH	0.02%	Not more than 0.10% w/w
10. ASSAY (By Titration)	100.03%	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	1.83 m ² /gm	For Information
RESIDUAL SOLVENTS (BY GC-HS)		
Toluene	149 ppm	Not more than 750 ppm
Methanol	109 ppm	Not more than 500 ppm
Isopropyl Alcohol	Not detected	Not more than 1000 ppm
Ethyl Acetate	0 ppm	Not more than 500 ppm
Bulk Density	0.27 g/ml	For Information
Tapped Density	0.53 g/ml	For Information

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

[Signature]
**Prepared by
 Executive-QC**

[Signature]
**Checked by
 Manager-QC**

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PIRAMAL ENTERPRISES LIMITED

Result Analysis Report

Sample Name:
DILTIAZEM HCL

SOP Name:
DILTIAZEM HCL

Measured:
20 January 2015 PM 05:07:16

Sample Source & type:
Factory = PHL

Measured by:
MAHESH

Analysed:
20 January 2015 PM 05:07:17

Sample bulk lot ref:
DIL/M-01315(FP-020-2015)

Result Source:
Measurement

Particle Name:
DILTIAZEM HCL

Accessory Name:
Scirocco 2000

Analysis model:
General purpose

Sensitivity:
Normal

Particle RI:
1.500

Absorption:
0.001

Size range:
0.020 to 2000.000 um

Obscuration:
4.77 %

Dispersant Name:

Dispersant RI:
1.000

Weighted Residual:
0.836 %

Result Emulation:
Off

Concentration:
0.0004 %Vol

Span :
2.428

Uniformity:
0.75

Result units:
Volume

Specific Surface Area:
1.83 m²/g

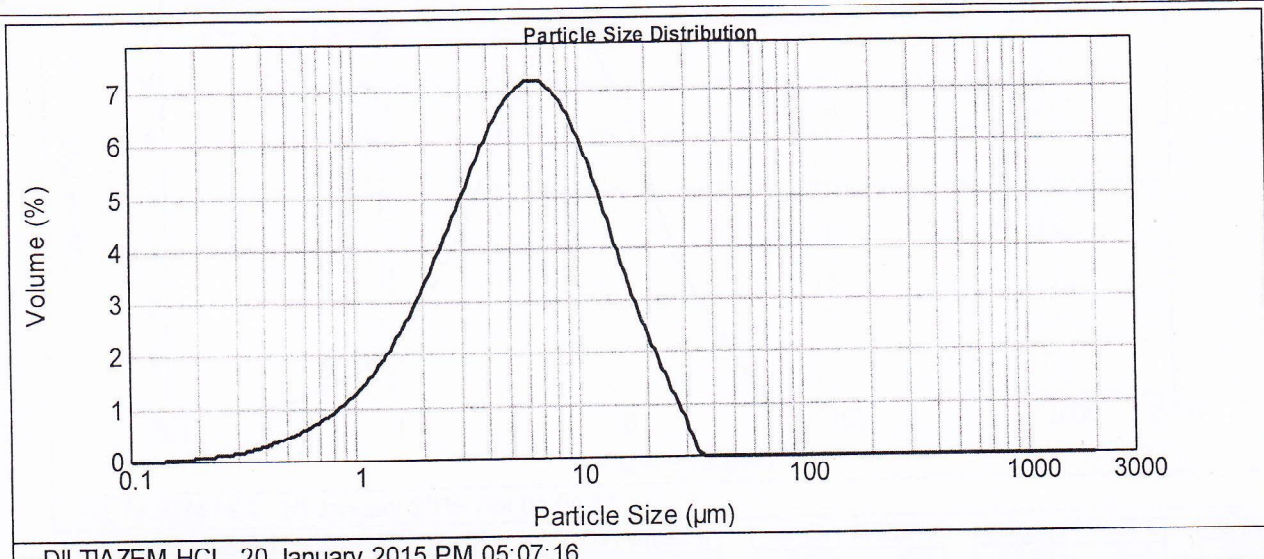
Surface Weighted Mean D[3,2]:
3.284 um

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

d(0.1): 1.602 um

d(0.5): 5.578 um

d(0.9): 15.147 um



Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %
0.017	0.00	2.188	16.03	6.600	70.01	21.000	96.35	130.030	100.00	831.764	100.00
0.026	0.00	2.512	19.52	9.411	73.86	22.000	96.99	149.400	100.00	954.993	100.00
0.158	0.01	2.884	23.56	9.900	75.94	23.000	97.54	150.011	100.00	1096.478	100.00
0.275	0.20	3.311	28.18	10.000	76.35	26.303	98.86	160.000	100.00	1258.925	100.00
0.316	0.32	3.802	33.34	10.200	77.13	34.674	100.00	174.000	100.00	1445.440	100.00
0.363	0.48	4.365	39.01	10.800	79.33	39.005	100.00	181.970	100.00	1659.587	100.00
0.417	0.70	5.012	45.09	11.682	82.18	43.452	100.00	208.930	100.00	1905.461	100.00
0.479	1.01	5.754	51.45	12.475	84.40	45.012	100.00	239.883	100.00	2187.762	100.00
0.631	1.90	6.930	60.17	13.062	85.85	69.824	100.00	275.423	100.00	2511.886	100.00
0.724	2.51	7.390	63.16	13.800	87.49	85.000	100.00	316.228	100.00	2884.032	100.00
0.832	3.28	7.458	63.59	14.465	88.80	97.900	100.00	363.078	100.00	3311.311	100.00
0.955	4.22	7.578	64.32	15.000	89.75	99.850	100.00	416.869	100.00	3801.894	100.00
1.066	5.37	7.874	66.07	15.790	91.02	100.000	100.00	478.630	100.00	5011.872	100.00
1.259	6.77	8.020	66.90	16.308	91.76	119.020	100.00	549.541	100.00	6606.934	100.00
1.660	10.57	8.210	67.95	17.659	93.44	125.000	100.00	630.957	100.00	7585.776	100.00
1.905	13.06	8.500	69.49	18.010	93.82	126.251	100.00	724.436	100.00	10000.000	100.00

Analysed by:

20/01/15

Checked by:

7cl
23/01/15