

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)		COMPENDIA : Ph.Eur.-8.0
BATCH NO. : DIL/M-00915		QUANTITY : 500 Kg
MFG. DATE : JANUARY.2015		EXP. DATE : DECEMBER.2019
QC A.R. No.: FP/016/2015		
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		
04. pH	Clear and colourless	Clear and colourless.
05. SPECIFIC OPTICAL ROTATION	4.7	4.3 to 5.3
06. RELATED SUBSTANCES	+119°	+ 115° to + 120°
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	0.23%	Not more than 0.50% w/w
09. SULPHATED ASH	0.03%	Not more than 0.10% w/w
10. ASSAY (By Titration)	100.01%	Not less than 98.50% w/w and Not more than 101.00% w/w
(On dried basis)		
ADDITIONAL TEST:		
PARTICLE SIZE		
100%	70 Microns	100% Less than 100 Microns
Surface Area	1.63 m ² /gm	For Information
RESIDUAL SOLVENTS (BY GC-HS)		
Toluene	161 ppm	Not more than 750 ppm
Methanol	172 ppm	Not more than 500 ppm
Isopropyl Alcohol	5 ppm	Not more than 1000 ppm
Ethyl Acetate	Not detected	Not more than 500 ppm
Bulk Density	0.28 g/ml	For Information
Tapped Density	0.53 g/ml	For Information

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

Seen
Prepared by
Executive-QC

[Signature]
Checked by
Manager-QC

[Signature]
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-00915(FP-016-2015)

SOP Name:
DILTIAZEM HCL

Measured by:
MAHESH

Result Source:
Measurement

Measured:
20 January 2015 PM 04:55:14

Analysed:
20 January 2015 PM 04:55:16

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 μ m

Weighted Residual:
0.376 %

Sensitivity:
Normal

Obscuration:
4.93 %

Result Emulation:
Off

Concentration:
0.0005 %Vol

Span :
2.714

Uniformity:
0.855

Result units:
Volume

Specific Surface Area:
1.63 m^2/g

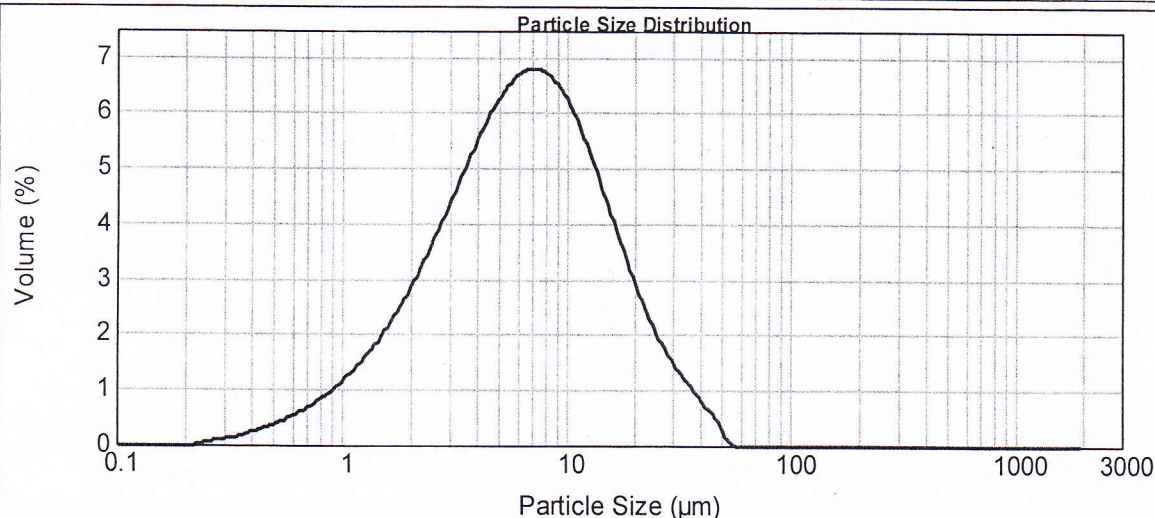
Surface Weighted Mean D[3,2]:
3.676 μ m

Vol. Weighted Mean D[4,3]:
8.765 μ m

d(0.1): 1.716 μ m

d(0.5): 6.339 μ m

d(0.9): 18.918 μ m



— DILTIAZEM HCL, 20 January 2015 PM 04:55:14

Size (μ m)	Vol Under %	Size (μ m)	Vol Under %	Size (μ m)	Vol Under %	Size (μ m)	Vol Under %	Size (μ m)	Vol Under %	Size (μ m)	Vol Under %
0.017	0.00	2.188	14.32	8.600	63.47	21.000	92.05	130.030	100.00	831.764	100.00
0.026	0.00	2.512	17.37	9.411	67.32	22.000	92.86	149.400	100.00	954.993	100.00
0.158	0.00	2.884	20.90	9.900	69.43	23.000	93.58	150.011	100.00	1096.478	100.00
0.275	0.06	3.311	24.93	10.000	69.84	26.303	95.45	160.000	100.00	1258.925	100.00
0.316	0.16	3.802	29.47	10.200	70.64	34.674	98.15	174.000	100.00	1445.440	100.00
0.363	0.29	4.365	34.50	10.800	72.92	39.005	98.94	181.970	100.00	1659.587	100.00
0.417	0.48	5.012	39.97	11.682	75.90	43.452	99.47	208.930	100.00	1905.461	100.00
0.479	0.75	5.754	45.78	12.475	78.27	45.012	99.61	239.883	100.00	2187.762	100.00
0.631	1.56	6.930	53.95	13.062	79.85	69.824	100.00	275.423	100.00	2511.886	100.00
0.724	2.13	7.390	56.80	13.800	81.65	85.000	100.00	316.228	100.00	2884.032	100.00
0.832	2.85	7.458	57.21	14.465	83.10	97.900	100.00	363.078	100.00	3311.311	100.00
0.955	3.72	7.578	57.92	15.000	84.18	99.850	100.00	416.869	100.00	3801.894	100.00
1.096	4.79	7.874	59.61	15.790	85.62	100.000	100.00	478.630	100.00	5011.872	100.00
1.259	6.08	8.020	60.42	16.308	86.48	119.020	100.00	549.541	100.00	6606.934	100.00
1.660	9.50	8.210	61.45	17.659	88.46	125.000	100.00	630.957	100.00	7585.776	100.00
1.905	11.71	8.500	62.96	18.010	88.92	126.251	100.00	724.436	100.00	10000.000	100.00

Analysed by:

Checked by: