

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)	COMPENDIA : Ph.Eur.-8.0
BATCH NO. : DIL/M-01215	QUANTITY : 500 Kg
MFG. DATE : JANUARY.2015	EXP. DATE : DECEMBER.2019
QC A.R. No.: FP/019/2015	
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

0.20%

Not more than 0.50% w/w

09. SULPHATED ASH

0.02%

Not more than 0.10% w/w

10. ASSAY (By Titration)

99.95%

Not less than 98.50% w/w and

(On dried basis)

Not more than 101.00% w/w

ADDITIONAL TEST:
PARTICLE SIZE

100%

45 Microns

100% Less than 100 Microns

Surface Area

 1.77 m²/gm

For Information

RESIDUAL SOLVENTS (BY GC-HS)

Toluene

163 ppm

Not more than 750 ppm

Methanol

120 ppm

Not more than 500 ppm

Isopropyl Alcohol

Not detected

Not more than 1000 ppm

Ethyl Acetate

1 ppm

Not more than 500 ppm

Bulk Density

0.29 g/ml

For Information

Tapped Density

0.55 g/ml

For Information

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

Sand
Prepared by
Executive-QC

[Signature]
Checked by
Manager-QC

[Signature]
Approved by
Manager-QC

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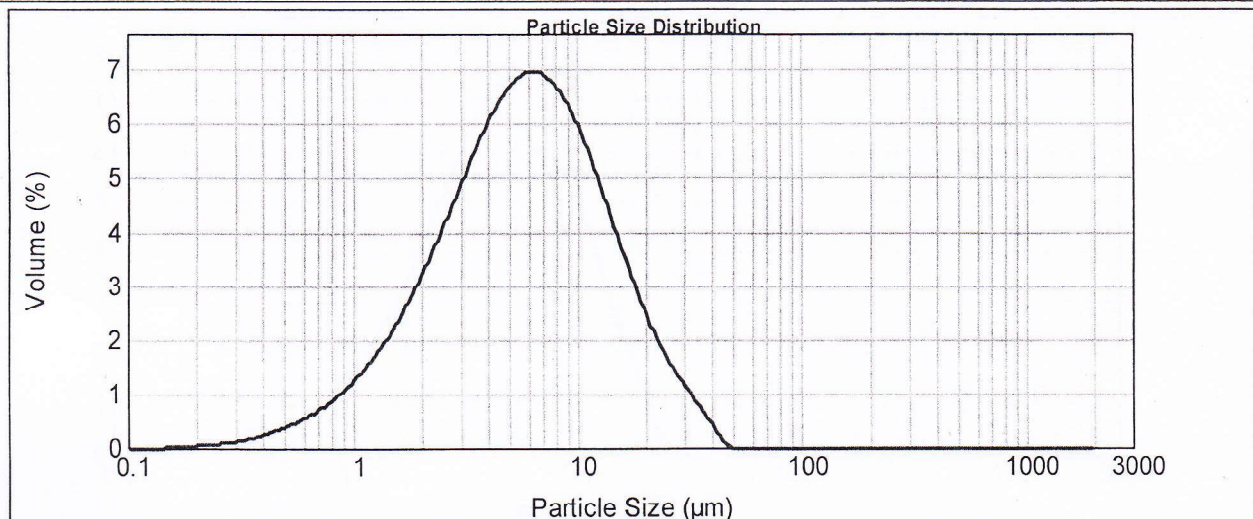
Result Analysis Report

Sample Name: DILTIAZEM HCL	SOP Name: DILTIAZEM HCL	Measured: 20 January 2015 PM 05:04:14
Sample Source & type: Factory = PHL	Measured by: MAHESH	Analysed: 20 January 2015 PM 05:04:16
Sample bulk lot ref: DIL/M-01215(FP-019-2015)	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: 5.71 %
Dispersant Name:	Dispersant RI: 1.000	Weighted Residual: 0.489 %	Result Emulation: Off

Concentration: 0.0005 %Vol	Span : 2.609	Uniformity: 0.818	Result units: Volume
Specific Surface Area: 1.77 m ² /g	Surface Weighted Mean D[3,2]: 3.395 um	Vol. Weighted Mean D[4,3]: 7.775 um	

d(0.1): 1.634 um d(0.5): 5.737 um d(0.9): 16.600 um



— DILTIAZEM HCL, 20 January 2015 PM 05:04:14

Size (um)	Vol Under %	Size (um)	Vol Under %	Size (um)	Vol Under %	Size (um)	Vol Under %	Size (um)	Vol Under %	Size (um)	Vol Under %
0.017	0.00	2.188	15.66	8.600	68.13	21.000	94.36	130.030	100.00	831.764	100.00
0.026	0.00	2.512	19.09	9.411	71.89	22.000	95.04	149.400	100.00	954.993	100.00
0.158	0.00	2.884	23.06	9.900	73.91	23.000	95.63	150.011	100.00	1096.470	100.00
0.275	0.17	3.311	27.56	10.000	74.31	26.303	97.15	160.000	100.00	1258.925	100.00
0.316	0.27	3.802	32.59	10.200	75.08	34.674	99.23	174.000	100.00	1445.440	100.00
0.363	0.41	4.365	38.09	10.800	77.24	39.005	99.72	181.970	100.00	1659.587	100.00
0.417	0.61	5.012	43.98	11.682	80.03	43.452	99.97	208.930	100.00	1905.461	100.00
0.479	0.88	5.754	50.14	12.475	82.22	45.012	100.00	239.883	100.00	2187.762	100.00
0.631	1.71	6.930	58.59	13.062	83.67	69.824	100.00	275.423	100.00	2511.886	100.00
0.724	2.30	7.390	61.48	13.800	85.30	85.000	100.00	316.228	100.00	2884.032	100.00
0.832	3.03	7.458	61.89	14.465	86.61	97.900	100.00	363.078	100.00	3311.311	100.00
0.955	3.95	7.578	62.61	15.000	87.57	99.850	100.00	416.869	100.00	3801.894	100.00
1.096	5.09	7.874	64.30	15.790	88.84	100.000	100.00	478.630	100.00	5011.872	100.00
1.259	6.48	8.020	65.11	16.308	89.60	119.020	100.00	549.541	100.00	6606.934	100.00
1.660	10.25	8.210	66.13	17.659	91.31	125.000	100.00	630.957	100.00	7585.776	100.00
1.905	12.73	8.500	67.63	18.010	91.71	128.251	100.00	724.436	100.00	10000.000	100.00

Analysed by: *[Signature]*
22/01/15

Checked by: *[Signature]*
23/01/15