

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)		COMPENDIA : Ph.Eur.-7.7
BATCH NO. : DIL/M-08514		QUANTITY : 500 Kg
MFG. DATE : MARCH.2014		EXP. DATE : FEBRUARY.2019
QC A.R. No.: FP/102/2014		
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 212°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 colorless	Clear and colourless.
04. pH	4.8	4.3 to 5.3
05. SPECIFIC OPTICAL ROTATION	+116°	+ 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	0.36%	Not more than 0.50% w/w
09. SULPHATED ASH	0.04%	Not more than 0.10% w/w
10. ASSAY (By Titration) (On dried basis)	100.82%	Not less than 98.50% w/w and Not more than 101.00% w/w
ADDITIONAL TEST:		
PARTICLE SIZE		
100%	26 Microns	100% Less than 100 Microns
Surface Area	1.9 m ² /gm	For Information
RESIDUAL SOLVENTS (BY GC-HS)		
Toluene	266 ppm	Not more than 750 ppm
Methanol	287 ppm	Not more than 500 ppm
Isopropyl Alcohol	6 ppm	Not more than 1000 ppm
Ethyl Acetate	24 ppm	Not more than 2500 ppm
Bulk Density	0.25 g/ml	For Information
Tapped Density	0.46 g/ml	For Information

REMARKS: The product conforms to **Ph.Eur.-7.7 & Customer's Specifications**

Deew
Prepared by
Executive-QC

Luqman
Checked by
Manager-QC

AB Sen
Approved by
General Manager-QC

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TRAMAL ENTERPRISES LIMITED

Result Analysis Report

Sample Name:
DILTIAZEM HCL

Sample Source & type:
Factory = PHL

Sample bulk lot ref:
DIL/M-08514(FP/102/2014)

SOP Name:
DILTIAZEM HCL

Measured by:
PHANI

Result Source:
Measurement

Measured:
25 April 2014 PM 02:45:58

Analysed:
25 April 2014 PM 02:45:59

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:
0.896 %

Sensitivity:
Normal

Obscuration:
6.68 %

Result Emulation:
Off

Concentration:
0.0006 %Vol

Span :
2.117

Uniformity:
0.65

Result units:
Volume

Specific Surface Area:
1.9 m²/g

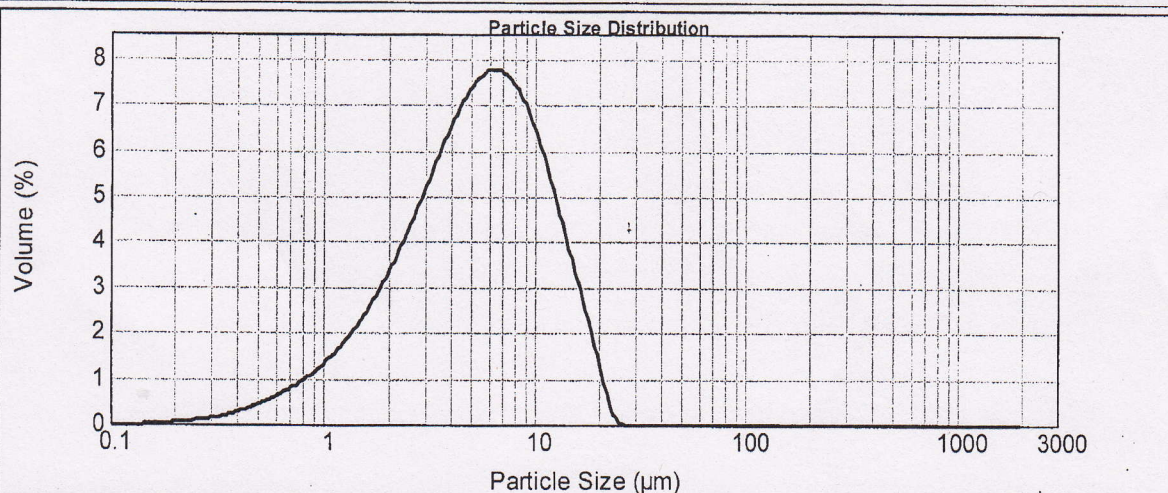
Surface Weighted Mean D[3,2]:
3.156 um

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

d(0.1): 1.551 um

d(0.5): 5.317 um

d(0.9): 12.804 um



DILTIAZEM HCL, 25 April 2014 PM 02:45:58

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	0.120	0.00	1.259	7.17	12.824	90.05	125.124	100.00	1258.925	100.00
0.011	0.00	0.138	0.00	1.660	11.11	14.000	92.62	142.650	100.00	1445.440	100.00
0.015	0.00	0.158	0.01	1.905	13.68	15.136	94.58	158.489	100.00	1659.587	100.00
0.017	0.00	0.182	0.03	2.188	16.72	17.378	97.31	181.970	100.00	1905.461	100.00
0.020	0.00	0.209	0.06	2.512	20.31	19.953	99.11	208.930	100.00	2187.762	100.00
0.023	0.00	0.240	0.12	2.894	24.48	22.909	99.91	239.883	100.00	2511.886	100.00
0.026	0.00	0.275	0.21	3.311	29.27	26.303	100.00	275.423	100.00	2884.032	100.00
0.030	0.00	0.316	0.32	3.802	34.67	30.200	100.00	316.228	100.00	3311.311	100.00
0.035	0.00	0.363	0.48	4.365	40.65	34.674	100.00	363.078	100.00	3801.894	100.00
0.040	0.00	0.417	0.72	5.012	47.12	39.811	100.00	416.869	100.00	4365.158	100.00
0.046	0.00	0.479	1.03	5.754	53.94	45.709	100.00	478.630	100.00	5011.872	100.00
0.052	0.00	0.550	1.45	6.607	60.94	52.481	100.00	549.541	100.00	5754.399	100.00
0.060	0.00	0.631	1.98	6.950	63.51	60.256	100.00	630.957	100.00	6606.934	100.00
0.069	0.00	0.724	2.64	8.125	71.28	69.183	100.00	724.436	100.00	7585.776	100.00
0.079	0.00	0.832	3.46	9.011	76.18	79.433	100.00	831.764	100.00	8709.636	100.00
0.091	0.00	0.955	4.48	10.000	80.79	85.124	100.00	954.993	100.00	10000.000	100.00
0.105	0.00	1.096	5.69	11.482	86.27	99.000	100.00	1096.478	100.00		

Analysed by:

25/04/14

Checked by:

MR
27/04/14