

## CERTIFICATE OF ANALYSIS

<b>PRODUCT : DILTIAZEM HCl (MICRONISED)</b>		<b>COMPENDIA : Ph.Eur.-7.7</b>
<b>BATCH NO. : DIL/M-11413</b>		<b>QUANTITY : 500 Kg</b>
<b>MFG. DATE : JUNE.2013</b>		<b>EXP. DATE : MAY.2018</b>
<b>QC A.R. No.: FP/139/2013</b>		
<b>TESTS</b>	<b>RESULTS</b>	<b>SPECIFICATIONS</b>
<b>01. CHARACTERS</b>		
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.
<b>02. IDENTIFICATION</b>		
IR Absorption	Concordant with working standard	IR Absorption spectrum of the sample is concordant with that of the Diltiazem hydrochloride CRS / working standard. It gives reaction to chlorides. Clear and colourless.
CHLORIDES	Positive	
<b>03. APPEARANCE OF SOLUTION</b>	Clear and colorless	
<b>04. pH</b>	4.9	4.3 to 5.3
<b>05. SPECIFIC OPTICAL ROTATION</b>	+118°	+ 115° to + 120°
<b>06. RELATED SUBSTANCES</b>		
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
<b>07. HEAVY METALS</b>	Less than 10 ppm	Not more than 10 ppm
<b>08. LOSS ON DRYING</b>	0.13%	Not more than 0.50% w/w
<b>09. SULPHATED ASH</b>	0.03%	Not more than 0.10% w/w
<b>10. ASSAY (By Titration)</b>	99.77%	Not less than 98.50% w/w and Not more than 101.00% w/w
<b>(On dried basis)</b>		
<b>ADDITIONAL TEST:</b>		
<b>PARTICLE SIZE</b>		
100%	25 Microns	100% Less than 100 Microns
<b>Surface Area</b>	1.92 m <sup>2</sup> /gm	For Information
<b>RESIDUAL SOLVENTS</b>		
Toluene	293 ppm	Not more than 750 ppm
Methanol	134 ppm	Not more than 500 ppm
Isopropyl Alcohol	Not detected	Not more than 1000 ppm
Ethyl Acetate	0 ppm	Not more than 2500 ppm
<b>Bulk Density</b>	0.28 g/ml	For Information
<b>Tapped Density</b>	0.54 g/ml	For Information

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

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