



# Piramal Healthcare Limited

knowledge action care

## CERTIFICATE OF ANALYSIS

<b>PRODUCT : DILTIAZEM HCl (Micronised)</b>		<b>COMPENDIA : JP XVI</b>
<b>BATCH NO. : DIL/M-08512</b>		<b>QUANTITY : 500 Kg</b>
<b>MFG. DATE : JUNE.2012</b>		<b>EXP. DATE : MAY.2017</b>
<b>QC A.R.No.: FP/258/2012</b>		
TESTS	RESULTS	SPECIFICATIONS
<b>01. DESCRIPTION</b>	White crystalline powder. It is very soluble in formic acid, freely soluble in water, in methanol and in chloroform, sparingly soluble in acetonitrile, slightly soluble in acetic anhydride and in ethanol (99.5%) and practically insoluble in diethyl ether.	White crystals or crystalline powder. It is very soluble in formic acid, freely soluble in water, in methanol and in chloroform, sparingly soluble in acetonitrile, slightly soluble in acetic anhydride and in ethanol (99.5%), and practically insoluble in diethyl ether.
<b>02. IDENTIFICATION</b>		
1. Reaction with Ammonium thiocyanate cobaltous nitrate	Conforms	To comply as per JP
2. Reaction of sulphates	Conforms	To comply as per JP
3. UV	Conforms	UV spectrum of sample and standard should exhibits similar intensities of absorption at the same wavelengths. The IR of the test sample exhibits absorption at the wave numbers of about 1741 cm <sup>-1</sup> , 1678 cm <sup>-1</sup> , 1252 cm <sup>-1</sup> , and 1025 cm <sup>-1</sup>
4. IR Spectrum	Conforms	To comply as per JP
5. Reaction of chloride	Conforms	Between +115° and +120°
<b>03. OPTICAL ROTATION</b>	+ 117°	210° to 215° C(with Decomposition)
<b>04. MELTING POINT</b>	213° C (with decomposition)	Between 4.3 to 5.3
<b>05. pH</b>	4.9	The solution is clear and colourless.
<b>06. CLARITY AND COLOUR OF SOLUTION</b>	Clear and colorless	
<b>07. SULFATES</b>	Less than 0.024%	Not more than 0.024%
<b>08. HEAVY METALS</b>	Less than 10 ppm	Not more than 10 ppm
<b>09. ARSENIC</b>	Less than 2 ppm	Not more than 2 ppm
<b>10. RELATED SUBSTANCES (By HPLC)</b>		
Total impurities	0.1%	Not more than 0.3%
<b>11. LOSS ON DRYING</b>	0.3%	Not more than 0.5% w/w
<b>12. RESIDUE ON IGNITION</b>	0.0%	Not more than 0.1% w/w
<b>13. ASSAY (On dry basis)</b>	100.0%	Not less than 98.5% w/w
<b>ADDITIONAL TESTS:</b>		
<b>PARTICLE SIZE</b>		
100%	34 Microns	100% Less than 100 Microns
<b>Surface Area</b>	1.96 m <sup>2</sup> /gm	For Information
<b>RESIDUAL SOLVENTS</b>		
Toluene	286 ppm	Not more than 750 ppm
Methanol	71 ppm	Not more than 500 ppm
Isopropyl Alcohol	04 ppm	Not more than 1000 ppm
Ethyl Acetate	04 ppm	Not more than 2500 ppm
<b>Bulk Density</b>	0.27 g/ml	For Information
<b>Tapped Density</b>	0.44 g/ml	For Information

**REMARKS:** The product conforms to JP XVI & Customer's Specifications.

Prepared by  
Executive-QC

Checked by  
Executive-QC

Approved by  
Manager-QC

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## CERTIFICATE OF ANALYSIS

<b>PRODUCT : DILTIAZEM HCl (MICRONISED)</b>		<b>COMPENDIA : Ph.Eur.-7.4</b>
<b>BATCH NO. : DIL/M-08512</b>		<b>QUANTITY : 500 Kg</b>
<b>MFG. DATE : JUNE.2012</b>		<b>EXP. DATE : MAY.2017</b>
<b>QC A.R. No.: FP/258/2012</b>		
TESTS	RESULTS	SPECIFICATIONS
<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.
CHLORIDES	Conforms	It gives reaction to chlorides.
<b>03. APPEARANCE OF SOLUTION</b>	Clear and colorless	Clear and colourless.
<b>04. pH</b>	4.9	4.3 to 5.3
<b>05. SPECIFIC OPTICAL ROTATION</b>	+117°	+ 115° to + 120°
<b>06. RELATED SUBSTANCES</b>		
i. Impurity F	Not Quantified	Not more than 0.2% 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>	0.31%	Not more than 0.50% w/w
<b>09. SULPHATED ASH</b>	0.02%	Not more than 0.10% w/w
<b>10. ASSAY (By Titration)</b>	99.92%	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%	34 Microns	100% Less than 100 Microns
<b>Surface Area</b>	1.96 m <sup>2</sup> /gm	For Information
<b>RESIDUAL SOLVENTS</b>		
Toluene	286 ppm	Not more than 750 ppm
Methanol	71 ppm	Not more than 500 ppm
Isopropyl Alcohol	04 ppm	Not more than 1000 ppm
Ethyl Acetate	04 ppm	Not more than 2500 ppm
<b>Bulk Density</b>	0.27 g/ml	For Information
<b>Tapped Density</b>	0.44 g/ml	For Information

**REMARKS:** The product conforms to **Ph.Eur.-7.4 & Customer's Specifications**

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**Prepared by  
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