

25 EN. x 20 KG.



Piramal Healthcare Limited

knowledge action care

### CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)		COMPENDIA : Ph.Eur.-7.4
BATCH NO. : DIL/M-07112		QUANTITY : 500 Kg
MFG. DATE : JUNE.2012		EXP. DATE : MAY.2017
QC A.R. No.: FP/203/2012		
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 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. It gives reaction to chlorides. Clear and colourless.
CHLORIDES	Conforms	4.3 to 5.3
03. APPEARANCE OF SOLUTION	Clear and colorless	+ 115° to + 120°
04. pH	4.8	
05. SPECIFIC OPTICAL ROTATION	+118°	
06. RELATED SUBSTANCES		
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
07. HEAVY METALS	Less than 10 ppm	Not more than 10 ppm
08. LOSS ON DRYING	0.25%	Not more than 0.50% w/w
09. SULPHATED ASH	0.04%	Not more than 0.10% w/w
10. ASSAY (By Titration)	100.19%	Not less than 98.50% w/w and Not more than 101.00% w/w
(On dried basis)		
ADDITIONAL TEST:		
PARTICLE SIZE		
100%	40 Microns	100% Less than 100 Microns
Surface Area	1.74 m <sup>2</sup> /gm	For information
RESIDUAL SOLVENTS		
Toluene	252 ppm	Not more than 750 ppm
Methanol	76 ppm	Not more than 500 ppm
Isopropyl Alcohol	08 ppm	Not more than 1000 ppm
Ethyl Acetate	01 ppm	Not more than 2500 ppm
Bulk Density	0.25 g/ml	For information
Tapped Density	0.50 g/ml	For information

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

Prepared by  
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### CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (Micronised)	COMPENDIA : JP XVI
BATCH NO. : DIL/M-07112	QUANTITY : 500 Kg
MFG. DATE : JUNE.2012	EXP. DATE : MAY.2017
QC A.R.No.: FP/203/2012	

TESTS	RESULTS	SPECIFICATIONS
01. DESCRIPTION	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.
02. IDENTIFICATION		To comply as per JP
1. Reaction with Ammonium thiocyanate cobaltous nitrate	Conforms	
2. Reaction of sulphates	Conforms	
3. UV	Conforms	To comply as per JP 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 Between +115° and +120° 210° to 215° C (with Decomposition) Between 4.3 to 5.3 The solution is clear and colourless.
5. Reaction of chloride	Conforms	
03. OPTICAL ROTATION	+ 118°	
04. MELTING POINT	213° C (with decomposition)	
05. pH	4.8	
06. CLARITY AND COLOUR OF SOLUTION	Clear and colorless	
07. SULFATES	Less than 0.024%	Not more than 0.024%
08. HEAVY METALS	Less than 10 ppm	Not more than 10 ppm
09. ARSENIC	Less than 2 ppm	Not more than 2 ppm
10. RELATED SUBSTANCES (By HPLC)		
Total impurities	0.0%	Not more than 0.3%
11. LOSS ON DRYING	0.2%	Not more than 0.5% w/w
12. RESIDUE ON IGNITION	0.0%	Not more than 0.1% w/w
13. ASSAY (On dry basis)	100.1%	Not less than 98.5% w/w
<b>ADDITIONAL TESTS:</b>		
PARTICLE SIZE		100% Less than 100 Microns
100%	40 Microns	For information
Surface Area	1.74 m <sup>2</sup> /gm	
<b>RESIDUAL SOLVENTS</b>		
Toluene	252 ppm	Not more than 750 ppm
Methanol	76 ppm	Not more than 500 ppm
Isopropyl Alcohol	08 ppm	Not more than 1000 ppm
Ethyl Acetate	01 ppm	Not more than 2500 ppm
Bulk Density	0.25 g/ml	For information
Tapped Density	0.50 g/ml	For information

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

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