



Piramal | Healthcare

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CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)		COMPENDIA : Ph.Eur.-7.7
BATCH NO. : DIL/M-02914		QUANTITY : 500 Kg
MFG. DATE : FEBRUARY.2014		EXP. DATE : JANUARY.2019
QC A.R. No.: FP/038/2014		
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 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.
CHLORIDES	Positive	Clear and colourless.
03. APPEARANCE OF SOLUTION	Clear and colorless	4.3 to 5.3
04. pH	4.8	+ 115° to + 120°
05. SPECIFIC OPTICAL ROTATION	+118°	
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	0.32%	Not more than 0.50% w/w
09. SULPHATED ASH	0.02%	Not more than 0.10% w/w
10. ASSAY (By Titration)	100.31%	Not less than 98.50% w/w and Not more than 101.00% w/w
(On dried basis)		
ADDITIONAL TEST:		
PARTICLE SIZE		
100%	26 Microns	100% Less than 100 Microns
Surface Area	1.95 m ² /gm	For Information
RESIDUAL SOLVENTS (BY GC-HS)		
Toluene	351 ppm	Not more than 750 ppm
Methanol	182 ppm	Not more than 500 ppm
Isopropyl Alcohol	3 ppm	Not more than 1000 ppm
Ethyl Acetate	2 ppm	Not more than 2500 ppm
Bulk Density	0.28 g/ml	For Information
Tapped Density	0.51 g/ml	For Information

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

Prepared by
Executive-QC

Checked by
Manager-QC

Approved by
General Manager-QC

Piramal Enterprises Limited

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CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)		COMPENDIA : JP XVI
BATCH NO. : DIL/M-02914		QUANTITY : 500 Kg
MFG. DATE : FEBRUARY.2014		EXP. DATE : JANUARY.2019
QC A.R.No.: FP/038/2014		
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		
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.
4. IR Spectrum	Conforms	The IR of the test sample exhibits absorption at the wave numbers of about 1741 cm ⁻¹ , 1678 cm ⁻¹ , 1252 cm ⁻¹ , and 1025 cm ⁻¹
5. Reaction of chloride	Positive	To comply as per JP
03. OPTICAL ROTATION	+ 117°	Between +115° and +120°
04. MELTING POINT	213° C (with decomposition)	210° to 215° C (with Decomposition)
05. pH	4.8	Between 4.3 to 5.3
06. CLARITY AND COLOUR OF SOLUTION	Clear and colorless	The solution is clear and colourless.
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	0.3%	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)	99.9%	Not less than 98.5% w/w
ADDITIONAL TESTS:		
PARTICLE SIZE		
100%	26 Microns	100% Less than 100 Microns
Surface Area	1.95 m ² /gm	For Information
RESIDUAL SOLVENTS		
Toluene	351 ppm	Not more than 750 ppm
Methanol	182 ppm	Not more than 500 ppm
Isopropyl Alcohol	3 ppm	Not more than 1000 ppm
Ethyl Acetate	2 ppm	Not more than 2500 ppm
Bulk Density	0.28 g/ml	For Information
Tapped Density	0.51 g/ml	For Information

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

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