

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)		COMPENDIA : Ph.Eur.-7.7
BATCH NO. : DIL/M-15313		QUANTITY : 500 Kg
MFG. DATE : AUGUST.2013		EXP. DATE : JULY.2018
QC A.R. No.: FP/185/2013		
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.
CHLORIDES	Positive	It gives reaction to chlorides.
03. APPEARANCE OF SOLUTION	Clear and colorless	Clear and colourless.
04. pH	4.9	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	0.16%	Not more than 0.50% w/w
09. SULPHATED ASH	0.03%	Not more than 0.10% w/w
10. ASSAY (By Titration)	99.77%	Not less than 98.50% w/w and Not more than 101.00% w/w
(On dried basis)		
ADDITIONAL TEST:		
PARTICLE SIZE		
100%	22 Microns	100% Less than 100 Microns
Surface Area	1.87 m ² /gm	For Information
RESIDUAL SOLVENTS		
Toluene	259 ppm	Not more than 750 ppm
Methanol	94 ppm	Not more than 500 ppm
Isopropyl Alcohol	2 ppm	Not more than 1000 ppm
Ethyl Acetate	1 ppm	Not more than 2500 ppm
Bulk Density	0.27 g/ml	For Information
Tapped Density	0.47 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 : Ph.Eur.-7.7
BATCH NO. : DIL/M-14913		QUANTITY : 500 Kg
MFG. DATE : JULY.2013		EXP. DATE : JUNE.2018
QC A.R. No.: FP/178/2013		
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		
03. APPEARANCE OF SOLUTION	Positive	It gives reaction to chlorides.
04. pH	Clear and colorless	Clear and colourless.
05. SPECIFIC OPTICAL ROTATION	4.9	4.3 to 5.3
06. RELATED SUBSTANCES	+119°	+ 115° to + 120°
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	0.18%	Not more than 0.50% w/w
09. SULPHATED ASH	0.03%	Not more than 0.10% w/w
10. ASSAY (By Titration)	99.79%	Not less than 98.50% w/w and Not more than 101.00% w/w
(On dried basis)		
ADDITIONAL TEST:		
PARTICLE SIZE		
100%	68 Microns	100% Less than 100 Microns
Surface Area	1.66 m ² /gm	For Information
RESIDUAL SOLVENTS		
Toluene	240 ppm	Not more than 750 ppm
Methanol	73 ppm	Not more than 500 ppm
Isopropyl Alcohol	3 ppm	Not more than 1000 ppm
Ethyl Acetate	1 ppm	Not more than 2500 ppm
Bulk Density	0.27 g/ml	For Information
Tapped Density	0.49 g/ml	For Information

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

[Signature]
Prepared by
Executive-QC

[Signature]
Checked by
Manager-QC

[Signature]
Approved by
General Manager-QC

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