

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)	COMPENDIA : Ph.Eur.-7.7
BATCH NO. : DIL/M-11814	QUANTITY : 500 Kg
MFG. DATE : JUNE.2014	EXP. DATE : MAY.2019
QC A.R. No.: FP/144/2014	
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 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

Positive

It gives reaction to chlorides.

03. APPEARANCE OF SOLUTION

Clear and colourless

Clear and colourless.

04. pH

4.6

4.3 to 5.3

05. SPECIFIC OPTICAL ROTATION

+119°

+ 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

0.17%

Not more than 0.50% w/w

09. SULPHATED ASH

0.02%

Not more than 0.10% w/w

10. ASSAY (By Titration)

99.79%

Not less than 98.50% w/w and

(On dried basis)

Not more than 101.00% w/w

ADDITIONAL TEST:
PARTICLE SIZE

100%

26 Microns

100% Less than 100 Microns

Surface Area

 2.07 m²/gm

For Information

RESIDUAL SOLVENTS (BY GC-HS)

Toluene

271 ppm

Not more than 750 ppm

Methanol

73 ppm

Not more than 500 ppm

Isopropyl Alcohol

Not detected

Not more than 1000 ppm

Ethyl Acetate

0 ppm

Not more than 2500 ppm

Bulk Density

0.25 g/ml

For Information

Tapped Density

0.47 g/ml

For Information

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

[Signature]
Prepared by
Executive-QC

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Checked by
Manager-QC

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Approved by
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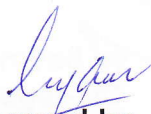
CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)		COMPENDIA : JP XVI
BATCH NO. : DIL/M-11814		QUANTITY : 500 Kg
MFG. DATE : JUNE.2014		EXP. DATE : MAY.2019
QC A.R.No.: FP/144/2014		
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. 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
4. IR Spectrum	Conforms	To comply as per JP
5. Reaction of chloride	Positive	Between +115° and +120°
03. OPTICAL ROTATION	+ 119°	210° to 215° C(with Decomposition)
04. MELTING POINT	212° C (with decomposition)	Between 4.3 to 5.3
05. pH	4.6	The solution is clear and colourless.
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	0.1%	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)	99.9%	Not less than 98.5% w/w
ADDITIONAL TESTS:		
PARTICLE SIZE		
100%	26 Microns	100% Less than 100 Microns
Surface Area	2.07 m²/gm	For Information
RESIDUAL SOLVENTS		
Toluene	271 ppm	Not more than 750 ppm
Methanol	73 ppm	Not more than 500 ppm
Isopropyl Alcohol	Not detected	Not more than 1000 ppm
Ethyl Acetate	0 ppm	Not more than 2500 ppm
Bulk Density	0.25 g/ml	For Information
Tapped Density	0.47 g/ml	For Information

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


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Manager-QC


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