

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)	COMPENDIA : Ph.Eur.-8.0
BATCH NO. : DIL/M-19914	QUANTITY : 500 Kg
MFG. DATE : DECEMBER.2014	EXP. DATE : NOVEMBER.2019
QC A.R. No.: FP/243/2014	
TESTS	RESULTS
	SPECIFICATIONS

01. CHARACTERS
i. Appearance

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 colourless

Clear and colourless.

04. pH

4.9

4.3 to 5.3

05. SPECIFIC OPTICAL ROTATION

+117°

+ 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

0.19%

Not more than 0.50% w/w

09. SULPHATED ASH

0.03%

Not more than 0.10% w/w

10. ASSAY (By Titration)

100.04%

Not less than 98.50% w/w and

(On dried basis)

Not more than 101.00% w/w

ADDITIONAL TEST:
PARTICLE SIZE

100%

85 Microns

100% Less than 100 Microns

Surface Area

 1.85 m²/gm

For Information

RESIDUAL SOLVENTS (BY GC-HS)

Toluene

232 ppm

Not more than 750 ppm

Methanol

142 ppm

Not more than 500 ppm

Isopropyl Alcohol

0 ppm

Not more than 1000 ppm

Ethyl Acetate

7 ppm

Not more than 500 ppm

Bulk Density

0.33 g/ml

For Information

Tapped Density

0.55 g/ml

For Information

REMARKS: The product conforms to **Ph.Eur.-8.0 & Customer's Specifications**

[Signature]
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