

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCI (MICRONISED)		COMPENDIA	: Ph.Eur8.0
BATCH NO. : DIL/M-15214	QUANTITY		: 500 Kg
MFG. DATE: JUNE.2014		EXP. DATE	: MAY.2019
	A D N		: WAY.2019
TESTS		o.: FP/182/2014	
01. CHARACTERS		RESULTS	SPECIFICATIONS
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		Freely soluble in water, in methanol and in methylene chloride, slightly soluble in
iii. Melting point	Melted	s ethanol. at 212°C with	anhydrous ethanol. Melts at about 213° C with
02. IDENTIFICATION	decompo	sition.	decomposition.
IR Absorption	Concordant with working standard		IR Absorption spectrum of the sample is concordant with that of the Diltiazem hydrochloride CRS /
CHLORIDES 03. APPEARANCE OF SOLUTION	Positive Clear and colourless		working standard. It gives reaction to chlorides. Clear and colourless.
04. pH	5.0		4.3 to 5.3
05. SPECIFIC OPTICAL ROTATION 06. RELATED SUBSTANCES	+118°		+ 115° to + 120°
i. Impurity F	Not Quar	.tifia.d	Not we are the end 0,000 and
ii. Unspecified Impurities	Not Quar		Not more than 0.3% w/w Not more than 0.10% w/w each
iii.Total Impurities	Not Quar		Not more than 0.10% w/w each
07. HEAVY METALS	Less than		Not more than 10 ppm
08. LOSS ON DRYING	0.20%		Not more than 0.50% w/w
09. SULPHATED ASH	0.03%		Not more than 0.10% w/w
10. ASSAY (By Titration)	99.97%		Not less than 98.50% w/w and
(On dried basis) ADDITIONAL TEST: PARTICLE SIZE			Not more than 101.00% w/w
100% Surface Area RESIDUAL SOLVENTS (BY GC-HS)	26 Micror 2.05 m ² /g		100% Less than 100 Microns For Information
Toluene	277 ppm		Not more than 750 ppm
Methanol	78 ppm		Not more than 750 ppm
Isopropyl Alcohol	1 ppm		Not more than 1000 ppm
Ethyl Acetate	0 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	o Ph.Eu	r8.0 & Custome	er's Specifications

Prepared by **Executive-QC**

Deedla Checked by **Executive-QC**

Approved by Manager-QC

Piramal Enterprises Limited

Factory: Digwal Village Kohir Mandal Medak Dist 502321 Andhra Pradesh India

T+91 8451 287508 F+91 8451 287553

Admin. Off: 5-9-30 Road # 4 Basheerbagh Palace Colony Basheerbagh Hyderabad 500 063 India T+91 40 2322 6719 F+91 40 2326 6041 / 82

Registered Office: Piramal Tower Peninsula Corporate Park Ganpatrao Kadam Marg Lower Parel Mumbai 400 013 T+91 22 3046 6666 F+91 22 2493 6708



CERTIFICATE OF ANALYSIS

BATCH NO.: DIL/M-15214 MFG. DATE: JUNE.2014 TESTS QC A.R.No.: FP/182/2014 TESTS RESULTS Notice crystalline powder. It is very soluble in formic acid, freely soluble in formic acid, freely soluble in formic acid, freely soluble in acetic anhydride and in ethanol (99.5%) and practically insoluble in acetic anhydride and in ethanol (99.5%) and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%), and practically insoluble in acetic anhydride and in ethanol (199.5%)			COMPENDIA	(MICRONISED)		PRODUCT :		
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Total impurities 0.1% Not more than 0.3%						09. ARSENIC		
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) 99.8% Not less than 98.5% w/w ADDITIONAL TESTS: PARTICLE SIZE		Not less than 98.5% w/w	Ν	99.8%	AL TESTS:	ADDITIONAL		
100% Less than 100 Microns		100% Less than 100 Microns	1	26 Microns		100%		
Surface Area 2.05 m ² /gm For Information RESIDUAL SOLVENTS		For Information	F			Surface Area		
Toluene 277 ppm Not more than 750 ppm		Not more than 750 ppm	N	277 ppm				
Methanol 78 ppm Not more than 500 ppm		Not more than 500 ppm	N	78 ppm		Methanol		
Isopropyl Alcohol 1 ppm Not more than 1000 ppm					cohol	Isopropyl Alco		
Ethyl Acetate 0 ppm Not more than 2500 ppm				0 ppm				
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Prepared by Executive-QC

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Approved by Manager-QC

Piramal Enterprises Limited

Factory: Digwal Village Kohir Mandal Medak Dist 502321 Andhra Pradesh India T +91 8451 287508 F +91 8451 287553

Admin. Off: 5-9-30 Road # 4 Basheerbagh Palace Colony Basheerbagh Hyderabad 500 063 India

T +91 40 2322 6719 F +91 40 2326 6041 / 82

Registered Office: Piramal Tower Peninsula Corporate Park Ganpatrao Kadam Marg Lower Parel Mumbai 400 013

T +91 22 3046 6666 F +91 22 2493 6708

W www.piramalhealthcare.com