

CERTIFICATE OF ANALYSIS

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PRODUCT : DILTIAZEM HCI (MICRONISED)		COMPENDIA	: Ph.Eur7.7	
BATCH NO. : DIL/M-16113		QUANTITY	: 500 Kg	
MFG. DATE: SEPTEMBER.20	13	EXP. DATE	: AUGUST.2018	
QC A.R. No.: FP/195/2013				
TESTS		RESULTS	SPECIFICATIONS	
01. CHARACTERS			J. Zon Idanono	
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	
	anhydrou	siigniiy soluble in s ethanol.	chloride, slightly soluble in	
iii. Melting point	Melted decompo	at 213°C with	anhydrous ethanol. Melts at about 213° C with decomposition.	
02. IDENTIFICATION		510011.	decomposition.	
IR Absorption	Concorda standard	int with working	IR Absorption spectrum of the sample is concordant with that of the Diltiazem hydrochloride CRS /	
CHLORIDES	Positive		working standard	
03. APPEARANCE OF SOLUTION	Clear and colorless		It gives reaction to chlorides. Clear and colourless.	
04. pH	4.9		4.3 to 5.3	
05. SPECIFIC OPTICAL ROTATION	+117°		+ 115° to + 120°	
06. RELATED SUBSTANCES			113 10 + 120	
i. Impurity F	Not Quan	tified	Not more than 0.3% w/w	
ii. Unspecified Impurities	Not Quant	tified	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	0.11%		Not more than 0.50% w/w	
09. SULPHATED ASH	0.03%		Not more than 0.10% w/w	
10. ASSAY (By Titration)	99.59%		Not less than 98.50% w/w and	
(On dried basis)			Not more than 101.00% w/w	
ADDITIONAL TEST: PARTICLE SIZE				
100%	34 Microns		100% Less than 100 Microns	
Surface Area	1.73 m ² /gr	n	For Information	
RESIDUAL SOLVENTS (BY GC-HS) Toluene				
Methanol	238 ppm		Not more than 750 ppm	
Isopropyl Alcohol	116 ppm Not detect	- 4	Not more than 500 ppm	
Ethyl Acetate	5 ppm	e u	Not more than 1000 ppm	
Bulk Density	0.27 g/ml		Not more than 2500 ppm For Information	
Tapped Density	0.49 g/ml		For Information	
DEMARKS, The send of the			- Or milorination	

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

Prepared by Executive-QC

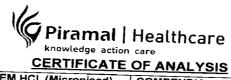
Checked by Manager-QC

Approved by Manager-QC

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PRODUCT : DILTIAZEM HCI (Micronised) COMPENDIA : IP YVII				
BATCH NO. : DIL/M-16113		COMPEND	<u></u> . 01 XV1	
MFG. DATE : SEPTEMBER.2013		QUANTITY		
		EXP. DATE	: AUGUST.2018	
TECTO QC A.R.No.: FP/195/2013				
01. DESCRIPTION	RESUL	TS	SPECIFICATIONS	
OI. DESCRIPTION	White crystalline pov	vder. It is very	White crystals or crystalline powder. It is	
	soluble in formic	acid freely	very soluble in formic acid, freely soluble	
	soluble in water. In	methanol and	in water, in methanol and in chloroform	
	in chloroform, sparingly soluble in		sparingly soluble in acetonitrile plicabile	
	acetonitrile, slightly soluble in		soluble in acetic anhydride and in	
	acetic anhydride and in ethanol (99.5%) and practically insoluble		ethanol (99.5%) and practically	
	in diethyl ether	any insoluble	insoluble in diethyl ether.	
02. IDENTIFICATION				
Reaction with Ammonium	Conforms		To comply as a second	
thiocyanate cobaltous nitrate			To comply as per JP	
Reaction of sulphates UV	Conforms		To comply as per JP	
J. 00	Conforms		UV spectrum of sample and standard	
			should exhibits similar intensities of	
4. IR Spectrum	Conforms		absorption at the same wavelengths	
	Comorns		THE IK Of the test sample exhibite	
•			absorption at the wave numbers of	
			about 1741 cm-1.1678 cm-1	
5. Reaction of chloride	Positive		1252 cm-1,and 1025 cm-1	
03. OPTICAL ROTATION	+ 117°		To comply as per JP	
04. MELTING POINT 05. ph	213° C (with decompo	sition)	Between +115° and +120° 210° to 215° C(with Decomposition)	
06. CLARITY AND COLOUR	4.9		Between 4.3 to 5.3	
OF SOLUTION	Clear and colorless		The solution is clear and colourless.	
07. SULFATES			solution is clear and colouriess.	
08. HEAVY METALS	Less than 0.024%		Not more than 0.024%	
09. ARSENIC	Less than 10 ppm Less than 2 ppm		Not more than 10 ppm	
10. RELATED SUBSTANCES (By HPI	C)		Not more than 2 ppm	
lotal impurities	0.0%			
11. LOSS ON DRYING	0.1%		Not more than 0.3%	
12. RESIDUE ON IGNITION	0.0%	,	Not more than 0.5% w/w	
13. ASSAY (On dry basis)	99.9%	,	Not more than 0.1% w/w Not less than 98.5% w/w	
ADDITIONAL TESTS: PARTICLE SIZE			Tot less than 98.5% W/W	
1000/				
O	34 Microns	1	00% Less than 100 Microns	
RESIDUAL SOLVENTS	1.73 m²/gm	F	or Information	
Telesan	238 ppm			
ivietnanoi	116 ppm	N	ot more than 750 ppm	
Isopropyi Alcohol	Not detected		lot more than 500 ppm	
⊏tnyi Acetate	5 ppm	N	lot more than 1000 ppm	
Bulk Density	0.27 g/mi	IN E	lot more than 2500 ppm or Information	
apped Density	140 0/ml		or Information or Information	
REMARKS: The product conform	ms to IP VVI & C.	242	or miornadon	

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

Prepared by Executive-QC

Checked by Manager-QC

Approved by Manager-QC

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