

CERTIFICATE OF ANALYSIS

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PRODUCT : DILTIAZEM HO (MICRONISED)	i	COMPENDIA	: Ph.Eur7.7		
BATCH NO. : DIL/M-16213					
MFG. DATE : SEPTEMBER.2	040	QUANTITY	: 360 Kg		
OLI ILMBER.2		EXP. DATE	: AUGUST.2018		
TEOTO QC A.R. No.: FP/196/2013					
01. CHARACTERS	F	RESULTS	SPECIFICATIONS		
i. Appearance			S. Edit IOA HONS		
	A white, o	crystalline powder.	White or almost white, crystalline		
ii. Solubility	Freely soluble in water,		powaer.		
	methanol	and in methylene	water.		
	chloride,	slightly soluble in	and in memylene		
iii. Melting point	anhydrous	s ethanol	chloride, slightly soluble in anhydrous ethanol.		
in meiting point	Meited	at 212°C with	Melts at about 213° C with		
02. IDENTIFICATION	decompos	sition.	decomposition.		
IR Absorption	_		F = -11.211.		
	Concordant with working		IR Absorption spectrum of the		
	standard		sample is concordant with that of		
-			the Diffiazem hydrochloride CDC /		
CHLORIDES	Positive		working standard		
03. APPEARANCE OF SOLUTION	Clear and	coloriese	It gives reaction to chlorides		
U4. pH	4.9	001011633	Clear and colourless.		
05. SPECIFIC OPTICAL ROTATION	+117°		4.3 to 5.3		
UB. RELATED SUBSTANCES	. , . ,		+ 115° to + 120°		
i. Impurity F	Not Quantit	fied	Mad		
ii. Unspecified Impurities	Not Quantit		Not more than 0.3% w/w		
iii. Total Impurities	Not Quantif	fied	Not more than 0.10% w/w each		
07. HEAVY METALS	Less than 1		Not more than 0.30% w/w		
08. LOSS ON DRYING	0.16%		Not more than 10 ppm		
09. SULPHATED ASH	0.03%		Not more than 0.50% w/w Not more than 0.10% w/w		
10. ASSAY (By Titration)	99.60%		Not loss than 0.10% w/w		
(On dried basis)			Not less than 98.50% w/w and Not more than 101.00% w/w		
ADDITIONAL TEST: PARTICLE SIZE			react more than 101.00% w/w		
100%					
Surface Area	25 Microns		100% Less than 100 Microns		
RESIDUAL SOLVENTS (BY GC-HS)	1.73 m ² /gm		For Information		
Toluene	200		The state of the s		
Methanoi	382 ppm		Not more than 750 ppm		
Isopropyl Alcohol	241 ppm 0 ppm		Not more than 500 ppm		
Ethyl Acetate	2 ppm		Not more than 1000 ppm		
Bulk Density	0.26 g/ml		Not more than 2500 ppm		
Tapped Density	0.40 = 41	,	or Information		
REMARKS: The product conforms to	Ph Fur -7	7 8 Cuetem	or Information		

forms to Ph.Eur.-7.7 & Customer's Specifications

Prepared by Executive-QC

Checked by Manager-QC

Approved by Manager-QC

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CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCI (Micronised) COMPENDIA : JP XVI				
DIL/M-16213		QUANTITY		
MFG. DATE : SEPTEMBER.2013		EXP. DATE		
	QC A.R.No.:	ED/196/2012	: AUGUST.2018	
TESTS	RESUL	TC		
01. DESCRIPTION	White crystalling	.13	SPECIFICATIONS	
02. IDENTIFICATION	White crystalline po soluble in formic soluble in water. In in chloroform, sparii acetonitrile, slightly acetic anhydride ar (99.5%) and practic in diethyl ether.	acid, freely methanol and ngly soluble in soluble in	White crystals or crystalline powder. It is very soluble in formic acid, freely soluble in water, in methanol and in chloroform, sparingly soluble in acetic anhydride and in ethanol (99.5%), and practically insoluble in diethyl ether.	
1. Reaction with Ammonium	Conforms		_	
thiocyanate cobaltous nitrat	e		To comply as per JP	
Reaction of sulphates UV	Conforms		To come	
S. 8 V	Conforms		To comply as per JP	
			UV spectrum of sample and standard	
4. IR Spectrum	Conforms		absorption at the same wavelengths. The IR of the test sample exhibits absorption at the wave purposes.	
5. Reaction of chloride			about 1741 cm-1,1678 cm-1, 1252 cm-1,and 1025 cm-1	
03. OPTICAL ROTATION	Positive		To comply as per JP	
34. MELTING POINT	+ 117°		Between +115° and +120°	
95. pH	212° C (with decompo	sition)	210° to 215° C(with Decomposition)	
6. CLARITY AND COLOUR	4.9		Between 4.3 to 5.3	
OF SOLUTION	Clear and colorless	-	The solution is clear and colourless.	
17. SULFATES	1		and colourless.	
8. HEAVY METALS	Less than 0.024%	1	Not more than 0.024%	
9. ARSENIC	Less than 10 ppm	١	Not more than 10 ppm	
O. RELATED SUBSTANCES (By	Less than 2 ppm		Not more than 2 ppm	
	0.0%			
1. LOSS ON DRYING	0.2%	7	Not more than 0.3%	
2. RESIDUE ON IGNITION	0.0%	N	lot more than 0.5% w/w	
J. ASSAY (On dry basis)	99.8%	N	lot more than 0.1% w/w	
PARTICLE SIZE	55.572	N	lot less than 98.5% w/w	
100%	25 Microns			
Surface Area	1.73 m ² /gm	7(00% Less than 100 Microns	
RESIDUAL SOLVENTS Toluene	3	F	or Information	
Methanoi	382 ppm			
Isopropyi Alcohol	241 ppm	No Ala	ot more than 750 ppm	
Ethyl Acetate	0 ppm	INC	ot more than 500 ppm	
Bulk Density	2 ppm	NO No	ot more than 1000 ppm	
Tapped Density	0.26 g/ml	INC	ot more than 2500 ppm	
EMARKS: The product conf	0.46 g/mi	Fo	r Information	

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

Prepared by Executive-QC

Checked by Manager-QC

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