

PHL-DG-QC-SPG-100025
QAD-F-3002-02
CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl		COMPENDIA : Ph.Eur. -10.0	
BATCH No. : DIL/M-19021		BATCH QUANTITY : 380.10 Kg	
MFG. DATE : MAY.2021		EXP. DATE : APRIL.2026	
APPROVED ON : 05/06/21		DISPATCH QUANTITY : 25.00 Kg	
INPUT BATCH No. : DIL3300321		QC A.R. No. : FP/152/2021	
Version No. : 00		Supersede No. : NA	
TESTS		RESULTS	SPECIFICATION
1. 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		It melted at 213°C with decomposition.	Melts at about 213° C with decomposition.
2. IDENTIFICATION			
IR Absorption		Concordant with working standard	IR Absorption spectrum of the sample concordant with that of the Diltiazem hydrochloride CRS / working standard.
CHLORIDES		Positive	It gives reaction to chlorides.
3. APPEARANCE OF SOLUTION		Clear and colourless	Clear and colourless.
4. pH		4.9	4.3 to 5.3
5. SPECIFIC OPTICAL ROTATION		+118°	+ 115° to + 120°
6. RELATED SUBSTANCES (By HPLC)			
i) Impurity F		Not Quantified	Not more than 0.3% w/w
ii) Unspecified Impurities		Not Quantified	Not more than 0.10% w/w
iii) Total Impurities		Not Quantified	Not more than 0.30% w/w
7. LOSS ON DRYING		0.17%	Not more than 0.50% w/w
8. SULPHATED ASH		0.02%	Not more than 0.10% w/w
9. ASSAY (By Titration) (On dried basis)		100.17%	Not less than 98.50% w/w and Not more than 101.00% w/w
ADDITIONAL TESTS:			
1. RESIDUAL SOLVENTS: (By GC-HS)			
Toluene		299 ppm	Not more than 750 ppm
Methanol		246 ppm	Not more than 500 ppm
Isopropyl Alcohol		8 ppm	Not more than 1000 ppm
Ethyl Acetate		1 ppm	Not more than 2500 ppm
Additional Information: NA			
REMARKS: The product conforms to Ph.Eur. -10.0 Specifications			
Prepared by Sign & Date Executive-QC/Team member		Checked by Sign & Date Executive-QC/Manager-QC	Approved by Sign & Date HOD-QC/Manager/Designee

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