Piramal

QCSPG100025-F02-01

CERTIFICATE OF ANALYSIS

PRODUCT	: DILTIAZEM HCl	COMPENDIA	: Ph.Eur. -11.0
BATCH No.	: DIL/M06925	BATCH QUANTITY	: 385.17 Kg
MFG. DATE	: MARCH.2025	EXP. DATE	: FEBRUARY.2030
INPUT BATCH No.	: DIL3307025	QC A.R. No.	: FP/062/2025
Version No.	: 00	Supersede No.	: NA

BATCH APPROVED ON : 27/03/25

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	4.7	4.3 to 5.3
5. SPECIFIC OPTICAL ROTATION	+117°	+ 115° to + 120°
6. RELATED SUBSTANCES (By HPLC)		
i) Impurity F	Not Quantified	Not more than 0.3% w/w
ii) Unspecified Impurities	0.06%	Not more than 0.10% w/w
iii) Total Impurities	0.06%	Not more than 0.30% w/w
7. LOSS ON DRYING	0.19%	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)	99.98%	Not less than 98.50% w/w and Not more than 101.00% w/w
ADDITIONAL TESTS:		
1. RESIDUAL SOLVENTS: (By GC-HS)		
Toluene	330 ppm	Not more than 750 ppm
Methanol	293 ppm	Not more than 500 ppm
Isopropyl Alcohol	0 ppm	Not more than 1000 ppm
Ethyl Acetate	1 ppm	Not more than 2500 ppm

Additional Information: NA

STP Number: PHL-DG-QC-DL-FPSTP-100002

Customer name : Magis-Pharma NV

DA Number: 1315041648 / PO Number : PO09420 DTD.25.02.2025

REMARKS: The product conforms to **Ph.Eur. -11.0** Specifications

07/04/25	08/04/25	08/04/25
Compiled by Sign & Date	**Reviewed by Sign & Date**	**Approved by Sign & Date**
Executive-QC/ Dy. Manager	**HOD-QC/ Manager/ Designee**	**HOD-QA/ Manager/ Designee:**