

PHL-DG-QC-SPG-100025 QAD-F-3002-02

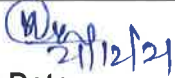
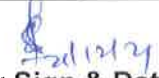

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl	COMPENDIA : USP-43
BATCH No. : DIL/M-22521	BATCH QUANTITY : 375.15 Kg
MFG. DATE : JULY.2021	EXPIRY DATE : JUNE.2026
APPROVED ON : 18/09/21	DISPATCH QUANTITY : 50.00 Kg
INPUT BATCH No. : DIL3308021	QC A.R. No. : FP/225/2021
Version No. : 00	Supersede No. : NA

TESTS	RESULTS	SPECIFICATION
1. DESCRIPTION	White, crystalline powder. Melts at 213° C with decomposition.	White, odorless, crystalline powder or small crystals. Melts at about 210° C with decomposition.
2. SOLUBILITY	Freely soluble in chloroform, in formic acid, in methanol and in water. Sparingly soluble in dehydrated alcohol, insoluble in ether.	Freely soluble in chloroform, in formic acid, in methanol and in water. Sparingly soluble in dehydrated alcohol; insoluble in ether.
3. IDENTIFICATION		
A. IR Absorption	Concordant with working standard.	The IR of the test sample is concordant with that of the working standard/Reference standard.
B. HPLC	Conforms	The retention time of the Diltiazem Hydrochloride peak in the chromatogram of the assay preparation corresponds to that of the chromatogram of the standard preparation, obtained under assay test.
C. Chlorides.	Positive	Gives positive test for chloride.
4. SPECIFIC ROTATION	+114°	Between +110° to +116°
5. LOSS ON DRYING	0.18%	Not more than 0.50% w/w
6. RESIDUE ON IGNITION	0.04%	Not more than 0.10% w/w
7. RELATED SUBSTANCES (By HPLC)		
1. Desacetyl Diltiazem HCl	0.04%	Not more than 0.30%
2. Unknown Individual impurity	0.03%	Not more than 0.10%
3. Total impurities	0.08%	Not more than 0.50%
8. RESIDUAL SOLVENTS (By GC-MS)		
CLASS - 2. Residual Solvents		
a) Toluene	555 ppm	Not more than 750 ppm
b) Methanol	246 ppm	Not more than 500 ppm
CLASS - 3. Residual Solvents		
a) Isopropyl Alcohol	1 ppm	Not more than 1000 ppm
b) Ethyl Acetate	0 ppm	Not more than 500 ppm
9. ASSAY (By HPLC) (On dried basis)	99.5%	Not less than 98.0% w/w and Not more than 102.0% w/w of C ₂₂ H ₂₆ N ₂ O ₄ S. HCl.

Additional Information: NA

Remarks: The product conforms to **USP-43** 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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Piramal Pharma Limited

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