KalChem INTERNATIONAL
Compounding Chemicals You Can Trust

Piramal

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-HS)		
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 $C_{22}H_{26}N_2O_4S$ HCl.

Additional Information: NA

Remarks: The product conforms to **USP-43** specifications.

Prepared by Sign & Date	Checked by Sign & Date	Approved by Sign & Date
Executive-QC/Team member	Executive-QC/Manager-QC	HOD-QC/Manager/Designee:

Piramal Pharma Limited
CIN No.: U24297MH2020PLC338592
Factory Address: Sy. Nos. 7-70, 70/1 and 70/2, Digwal Village, Kohir Mandal, Sangareddy District - 502 321, Telangana, India. T 08451 - 350 999 / 276800
Admin Office: 5-9-30, Road # 4, Basheerbagh Palace Colony, Basheerbagh, Hyderabad - 500 063, Telangana, India. T 040 - 23226719
Registered Office: Gr.Flr., Piramal Ananta, Agastya Corporate Park, Kamani Junction, LBS Marg, Kurla, Mumbai - 400 070, India. T 022 - 3046 6666
piramalpharmasolutions.com