

CERTIFICATE OF ANALYSIS

(Certificate No. KMD015017-01)

Release Date: 23/05/2025

Re-test Date: 22/05/2028

DILTIAZEM RELATED COMPOUND A

Identification

Chemical Name :

(2R,3S)-5-[2-(Dimethylamino)ethyl]-2-(4-methoxyphenyl)-4-oxo-2,3,4,5-tetrahydro-1,5-benzothiazepin-3-yl acetate hydrochloride (as per EP & USP)

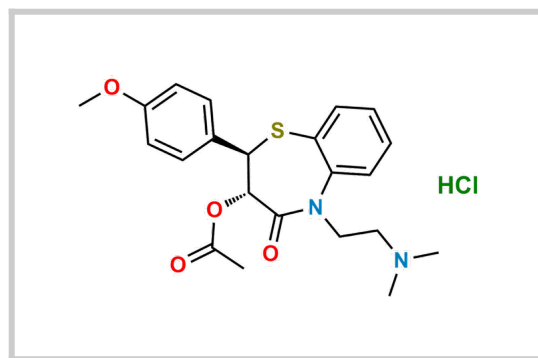
Alt. Name : Diltiazem USP Related Compound A
; trans-Diltiazem hydrochloride (USP)
; Diltiazem (2R)-Isomer

CAT No. : KMD015017

CAS No. : 103532-27-0

Molecular Formula : C₂₂H₂₆N₂O₄S : HCl

Molecular Weight : 414.5 : 36.5



Analytical Information

Batch No. : DIL-RC-A-045-363

Description : Light Yellow Solid

HPLC Purity : 94.34 %

Weight Loss By TGA : 3.49 %

% Potency : 91.05 %

Solubility : Acetonitrile

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 3.49(Weight Loss By TGA)] x [94.34(HPLC Purity)]/100 = 91.05 %

-Re-tested on 23.05.2025

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 24/05/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 24/05/2025 |

Attachments : COA, HPLC, MASS, ¹HNMR, IR and TGA