

CERTIFICATE OF ANALYSIS

(Certificate No. KMB037005-01)

Release Date: 06/12/2024

Re-test Date: 05/12/2027

Benazepril Related Compound A

Identification

Chemical Name :

(3R)-3-[[[(1R)-1-(ethoxycarbonyl)-3-phenylpropyl]amino]-2,3,4,5-tetrahydro-2-oxo-1H-1-benzazepine-1-acetic acid hydrochloride

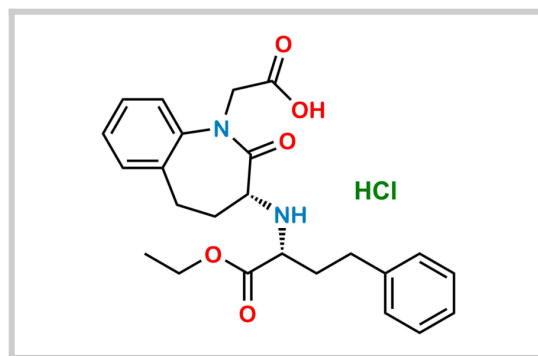
Alt. Name : Benazepril USP Related Compound A

CAT No. : KMB037005

CAS No. : 131064-75-0 (free base) :
215447-89-5 (HCl salt)

Molecular Formula : C₂₄H₂₈N₂O₅ : HCl

Molecular Weight : 424.5 : 36.5



Analytical Information

Batch No. : B037005-091-064

Description : Light Yellow Solid

HPLC Purity : 97.70 %

Weight Loss By TGA : 1.52 %

% Potency : 96.21 %

Solubility : Water : Methanol
(1:1)

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 - 1.52(Weight Loss By TGA)] x [97.70(HPLC Purity)]/100 = 96.21 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		06/12/2024
Reviewed & Approved By	Quality Control	Jatin Patel		06/12/2024

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