

CERTIFICATE OF ANALYSIS

(Certificate No. KML007012-01)

Release Date: 29/11/2024

Re-test Date: 28/11/2027

Lisinopril EP Impurity D

Identification

Chemical Name :

(2S)-2-[(3S,8aR)-3-(4-aminobutyl)-1,4-dioxohexahydropyrrolo[1,2-a]pyrazin-2(1H)-yl]-4-phenylbutanoic acid (as per EP)

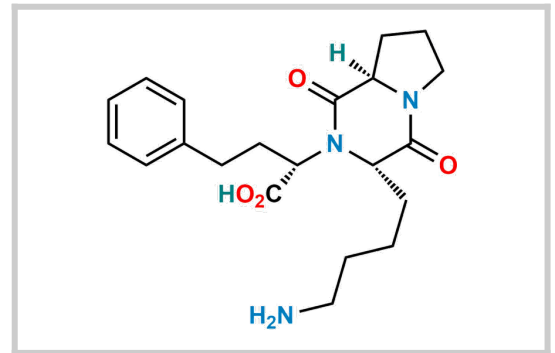
Alt. Name : R,S,S-diketopiperazine (EP)

CAT No. : KML007012

CAS No. : 219677-82-4

Molecular Formula : C₂₁H₂₉N₃O₄

Molecular Weight : 387.5



Analytical Information

Batch No. : L007012-091-050

Description : Off White Solid

HPLC Purity : 99.48 %

Weight Loss By TGA : 1.84 %

% Potency : 97.65 %

Solubility : ACN : Water (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 - 1.84(Weight Loss By TGA)] x [99.48(HPLC Purity)]/100 = 97.65 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		29/11/2024
Reviewed & Approved By	Quality Control	Jatin Patel		29/11/2024

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA