

CERTIFICATE OF ANALYSIS

(Certificate No. KML005030-01)

Release Date: 27/02/2025

Re-test Date: 26/02/2028

Losartan Potassium Impurity J

Identification

Chemical Name :

[2-Butyl-4-chloro-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-imidazol-5-yl]methyl acetate (as per EP)

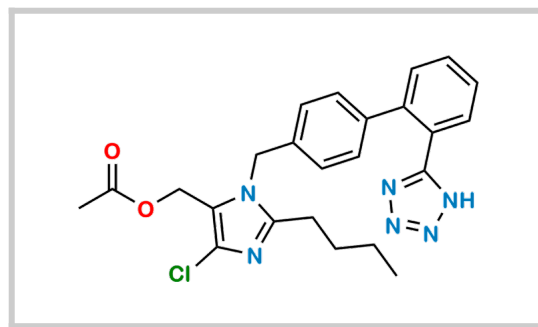
Alt. Name : Losartan USP Related Compound B ;
O-Acetyl Losartan ; Losartan Acetate

CAT No. : KML005030

CAS No. : 1006062-27-6

Molecular Formula : C₂₄H₂₅ClN₆O₂

Molecular Weight : 465.0



Analytical Information

Batch No. : LOS-EP-J-019-256

Solubility : Methanol

Description : Off white solid

Mass : Confirm

HPLC Purity : 91.94 %

IR : Confirm

Weight Loss By TGA : 0.64 %

¹H NMR : Confirm

% Potency : 91.35 %

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 - 0.64(Weight Loss By TGA)] x [91.94(HPLC Purity)]/100 = 91.35 %
-Re-tested on 27.02.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		28/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		28/02/2025

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