

CERTIFICATE OF ANALYSIS

(Certificate No. KMV008044-01)

Release Date: 27/09/2024

Re-test Date: 26/09/2027

Valsartan EP Impurity C

Identification

Chemical Name :
[(S-N-Butyryl-N-([2'-(1H-tetrazole-5-yl)biphen-4-yl)methyl)-valine

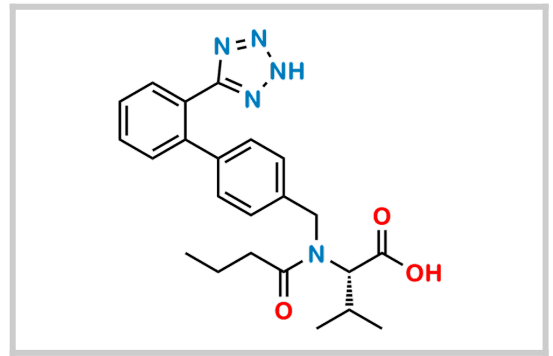
Alt. Name : Valsartan USP Related Compound B ;
Valsartan N-Butyryl Analog

CAT No. : KMV008044

CAS No. : 952652-79-8

Molecular Formula : C₂₃H₂₇N₅O₃

Molecular Weight : 421.5



Analytical Information

Batch No. : VAL/EP-C/023

Description : Brown Solid

HPLC Purity : 96.32 %

Weight Loss By TGA : 3.98 %

% Potency : 92.49 %

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 - 3.98(Weight Loss By TGA)] x [96.32(HPLC Purity)]/100 = 92.49 %
-Re-tested on 27.09.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		28/09/2024
Reviewed & Approved By	Quality Control	Jatin Patel		28/09/2024

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