

CERTIFICATE OF ANALYSIS

(Certificate No. KMI001002-01)

Release Date: 26/02/2024

Re-test Date: 25/02/2027

Irbesartan Impurity II

Identification

Chemical Name :

4'-((2-butyl-4-oxo-1,3-diazaspiro[4.4]non-1-en-3-yl)methyl)-[1,1'-biphenyl]-2-carbonitrile

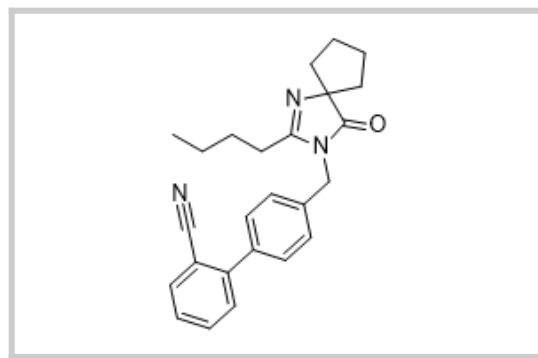
Alt. Name : Irbesartan Impurity B

CAT No. : KMI001002

CAS No. : 138401-24-8

Molecular Formula : C₂₅H₂₇N₃O

Molecular Weight : 385.50



Analytical Information

Batch No. : IRB-II-073-092

Description : Off White Solid

HPLC Purity : 95.51 %

Weight Loss By TGA : 1.42 %

% Potency : 94.15 %

Solubility : ACN

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 - 1.42(Weight Loss By TGA)] x [95.51(HPLC Purity)]/100 = 94.15 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Parag Patel		26/02/2024
Reviewed & Approved By	Quality Control	Jatin Patel		26/02/2024

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