CERTIFICATE OF ANALYSIS

(Certificate No. KMI001003-01)

Release Date: 12/03/2024 **Re-test Date:** 11/03/2027

Irbesartan Impurity III

Identification

Chemical Name :
2-Propyl-3-[p-(o-1H-tetrazol-5-ylphenyl)benzyl]-1,3-diazaspiro[4.4]non-1-en-4-one

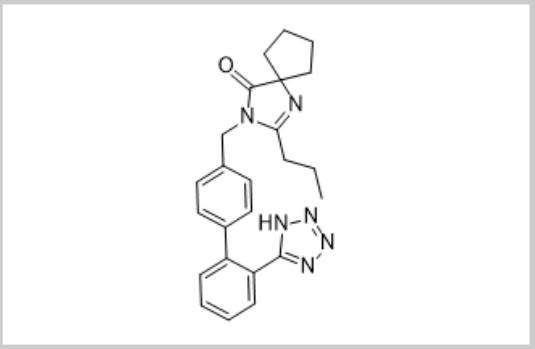
Alt. Name : Irbesartan Propyl Analog

CAT No. : KMI001003

CAS No. : 158778-58-6

Molecular Formula : C24H26N6O

Molecular Weight : 414.50



Analytical Information

Batch No.	: IRB-III-073-093	**Solubility**	: ACN : Water (1:1)
Description	: Off white solid	**Mass**	: Confirm
HPLC Purity	: 98.72 %	**IR**	: Confirm
Weight Loss By TGA	: 0.86 %	**1H NMR**	: Confirm
% Potency	: 97.87 %		

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 - 0.86(Weight Loss By TGA)] x [98.72(HPLC Purity)]/100 = 97.87 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Parag Patel		12/03/2024
Reviewed & Approved By	Quality Control	Jatin Patel		12/03/2024

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