

# 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

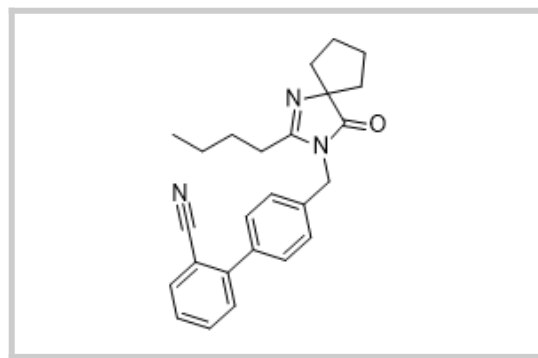
**Alt. Name** : Irbesartan Impurity B

**CAT No.** : KMI001002

**CAS No.** : 138401-24-8

**Molecular Formula** : C<sub>25</sub>H<sub>27</sub>N<sub>3</sub>O

**Molecular Weight** : 385.50



### Analytical Information

**Batch No.** : IRB-II-073-092

**Solubility** : ACN

**Description** : Off White Solid

**Mass** : Confirm

**HPLC Purity** : 95.51 %

**IR** : Confirm

**Weight Loss By TGA** : 1.42 %

**<sup>1</sup>H NMR** : Confirm

**% Potency** : 94.15 %

### 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, <sup>1</sup>HNMR, IR and TGA