

CERTIFICATE OF ANALYSIS

(Certificate No. KMI001037-02)

Release Date: 25/05/2026

Re-test Date: 24/05/2029

Irbesartan Lactam Impurity

Identification

Chemical Name :

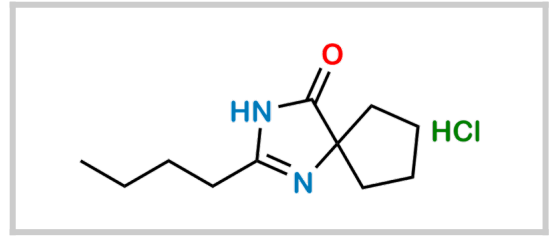
2-Butyl-1,3-diazaspiro[4.4]non-1-en-4-one Hydrochloride ; 2-Butyl-4-spirocyclopentane-2-imidazolin-5-one hydrochloride ;

CAT No. : KMI001037

CAS No. : 151257-01-1

Molecular Formula : C₁₁H₁₈N₂O : HCl

Molecular Weight : 194.3 : 36.5



Analytical Information

Batch No. : I001037-114-333

Description : Off White Solid

HPLC Purity : 99.12 %

Weight Loss By TGA : 0.16 %

% Potency : 98.96 %

Solubility : ACN : Water

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 - 0.16(Weight Loss By TGA)] x [99.12(HPLC Purity)]/100 = 98.96 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		25/05/2026
Reviewed & Approved By	Quality Control	Jatin Patel		25/05/2026

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