## **CERTIFICATE OF ANALYSIS**

(Certificate No. KMI001037-01)

**Release Date:** 15/09/2025 **Re-test Date:** 14/09/2028

# **Irbesartan Lactam Impurity**

### **Identification**

#### **Chemical Name:**

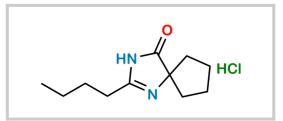
 $\hbox{2-Butyl-1,3-diazaspiro} \hbox{[4.4]} non-1-en-4-one \ Hydrochloride \ ; \hbox{2-Butyl-4-spirocyclopentane-2-imidazolin-5-one hydrochloride} \ ;$ 

**CAT No.** : KMI001037

**CAS No.** : 151257-01-1

Molecular Formula : C11H18N2O : HCl

 $\textbf{Molecular Weight} \hspace{0.5cm} : 194.3:36.5$ 



## **Analytical Information**

Description: Off White solidMass: ConfirmHPLC Purity: 99.94 %IR: ConfirmWeight Loss By TGA: 0.11 %1H NMR: Confirm

**% Potency** : 99.83 %

### **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 - 0.11(Weight Loss By TGA)] x [99.94(HPLC Purity)]/100 = 99.83 %

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Bhargav Kathiriya		15/09/2025
Reviewed & Approved By	Quality Control	Viraj Akabri		15/09/2025

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