

CERTIFICATE OF ANALYSIS

(Certificate No. KMC008075-01)

Release Date: 10/07/2025

Re-test Date: 09/07/2028

Regio Isomer Impurity of Cinacalcet HCl

Identification

Chemical Name :

N-(1-(Naphthalen-2-yl)ethyl)-3-(3-(trifluoromethyl)phenyl)propan-1-amine hydrochloride

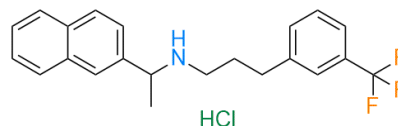
Alt. Name : Cinacalcet beta-Alkyl R-Isomer (HCl)

CAT No. : KMC008075

CAS No. : 2200269-28-7

Molecular Formula : C₂₂H₂₂F₃N : HCl

Molecular Weight : 357.4 : 36.5



Analytical Information

Batch No. : CIN-REG-ISO-019-115

Solubility : Methanol

Description : Off White Solid

Mass : Confirm

HPLC Purity : 99.18 %

IR : Confirm

Weight Loss By TGA : 0.68 %

¹H NMR : Confirm

% Potency : 98.51 %

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 - 0.68(Weight Loss By TGA)] x [99.18(HPLC Purity)]/100 = 98.51 %

-Re-tested on 10.07.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		16/07/2025
Reviewed & Approved By	Quality Control	Jatin Patel		16/07/2025

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