

CERTIFICATE OF ANALYSIS

(Certificate No. KMS008028-01)

Release Date: 23/12/2024

Re-test Date: 22/12/2027

Sorafenib Impurity C

Identification

Chemical Name :

4-[4-[[[2-chloro-3-(trifluoromethyl)phenyl]carbonyl]amino]phenoxy]-N-methylpyridine-2-carboxamide (as per EP); 4-(4-{3-[2-Chloro-3-(trifluoromethyl)phenyl]ureido}phenoxy)-N-methylpicolinamide (as per USP)

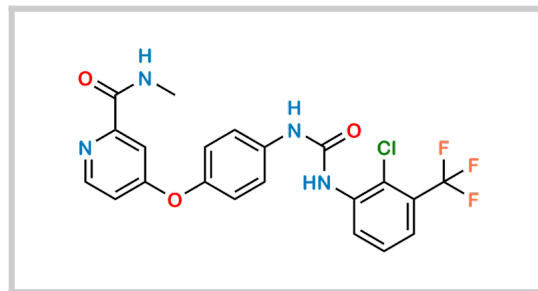
Alt. Name : Sorafenib USP Related Compound H

CAT No. : KMS008028

CAS No. : 1431697-81-2

Molecular Formula : C₂₁H₁₆ClF₃N₄O₃

Molecular Weight : 464.8



Analytical Information

Batch No. : SOR-IMP-D-030-025

Solubility : Methanol

Description : Brown Solid

Mass : Confirm

HPLC Purity : 97.37 %

IR : Confirm

Weight Loss By TGA : 0.18 %

¹H NMR : Confirm

% Potency : 97.19 %

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 - 0.18(Weight Loss By TGA)] x [97.37(HPLC Purity)]/100 = 97.19 %
-Re-tested on 23.12.2024.

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Parag Patel		25/12/2024
Reviewed & Approved By	Quality Control	Jatin Patel		25/12/2024

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