

CERTIFICATE OF ANALYSIS

(Certificate No. KMS002041-01)

Release Date: 03/01/2024

Re-test Date: 02/01/2027

Sildenafil EP Impurity A

Identification

Chemical Name :

5-[2-Ethoxy-5-[(4-methylpiperazin-1-yl)sulfonyl]phenyl]-1-methyl-3-(2-methylpropyl)-1,6-dihydro-7H-pyrazolo[4,3-d]pyrimidin-7-one,

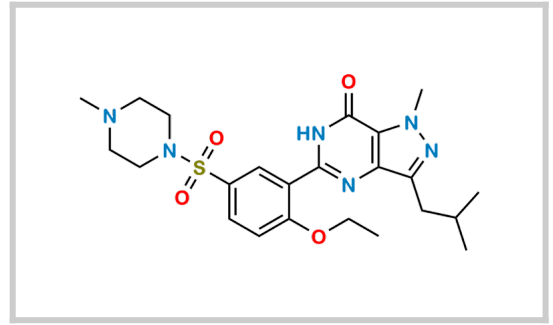
Alt. Name : Sildenafil USP RC A ; Sildenafil Isobutyl Analog

CAT No. : KMS002041

CAS No. : 1391053-95-4

Molecular Formula : C₂₃H₃₂N₆O₄S

Molecular Weight : 488.6



Analytical Information

Batch No. : SIL-IMP-A-045-298

Description : White Solid

HPLC Purity : 99.97 %

Weight Loss By TGA : 0.33 %

% Potency : 99.64 %

Solubility : ACN : Water (1:1)

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 - 0.33(Weight Loss By TGA)] x [99.97(HPLC Purity)]/100 = 99.64 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		27/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		27/03/2025

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