

CERTIFICATE OF ANALYSIS

(Certificate No. KMS002002-01)

Release Date: 15/03/2024

Re-test Date: 14/03/2027

Sildenafil EP Impurity F

Identification

Chemical Name :

5-(2-ethoxy-5-(piperazin-1-ylsulfonyl)phenyl)-1-methyl-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-7(4H)-one TFA salt

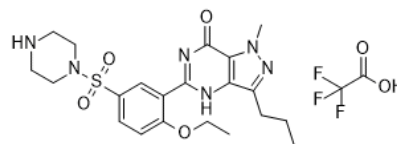
Alt. Name : N-Desmethyl Sildenafil

CAT No. : KMS002002

CAS No. : Not Available

Molecular Formula : C₂₁H₂₈N₆O₄S : C₂HF₃O₂

Molecular Weight : 460.55 : 114.02



Analytical Information

Batch No. : SIL-DES-ME-073-129

Solubility : ACN

Description : White Solid

Mass : Confirm

HPLC Purity : 99.97 %

IR : Confirm

Weight Loss By TGA : 1.39 %

¹H NMR : Confirm

% Potency : 98.58 %

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 - 1.39(Weight Loss By TGA)] x [99.97(HPLC Purity)]/100 = 98.58 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		15/03/2024
Reviewed & Approved By	Quality Control	Jatin Patel		15/03/2024

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