

CERTIFICATE OF ANALYSIS

(Certificate No. KMM020031-01)

Release Date: 04/02/2026

Re-test Date: 03/02/2029

N-Nitroso Mirtazapine EP Impurity D

Identification

Chemical Name :

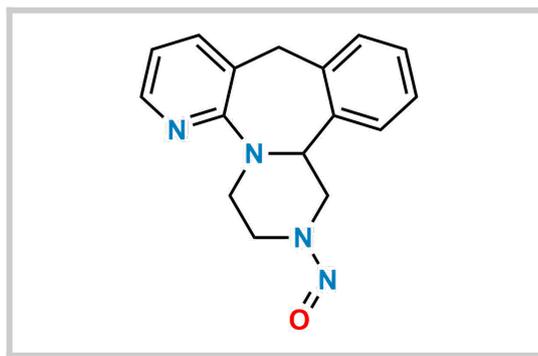
2-Nitroso-1,2,3,4,10,14b-hexahydrobenzo[c]pyrazino[1,2-a]pyrido[3,2-f]azepine

CAT No. : KMM020031

CAS No. : NA

Molecular Formula : C₁₆H₁₆N₄O

Molecular Weight : 280.3



Analytical Information

Batch No. : M020031-114-144

Description : Off White Solid

HPLC Purity : 99.80 %

Weight Loss By TGA : 0.29 %

% Potency : 99.51 %

Solubility : THF

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 - 0.29(Weight Loss By TGA)] x [99.80(HPLC Purity)]/100 = 99.51 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		10/02/2026
Reviewed & Approved By	Quality Control	Jatin Patel		10/02/2026

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA