

CERTIFICATE OF ANALYSIS

(Certificate No. KMS005021-01)

Release Date: 30/12/2023

Re-test Date: 29/12/2026

Solifenacin N-Oxide

Identification

Chemical Name :

(3R)-3-[[[(1S)-1-Phenyl-3,4-dihydroisoquinoline-2(1H)-carbonyl]oxy]-1-azabicyclo[2.2.2]octane 1-oxide (as per EP)

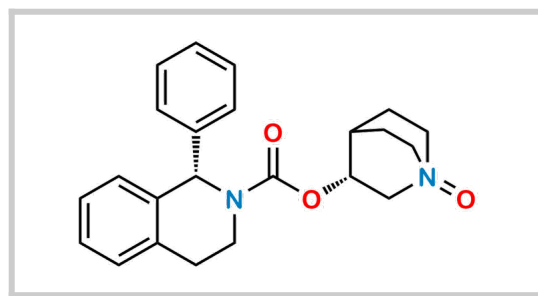
Alt. Name : Solifenacin N-Oxide (EP)

CAT No. : KMS005021

CAS No. : 180272-28-0

Molecular Formula : C₂₃H₂₆N₂O₃

Molecular Weight : 378.5



Analytical Information

Batch No. : SOL-N-OXIDE-073-009

Description : Off White Solid

HPLC Purity : 94.71 %

Weight Loss By TGA : 0.92 %

% Potency : 93.84 %

Solubility : Acetonitrile

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 - 0.92(Weight Loss By TGA)] x [94.71(HPLC Purity)]/100 = 93.84 %

Remarks : COA Re-generated on 06.01.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		06/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		06/01/2025

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