

CERTIFICATE OF ANALYSIS

(Certificate No. KMS005021-02)

Release Date: 29/05/2026

Re-test Date: 28/05/2029

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)

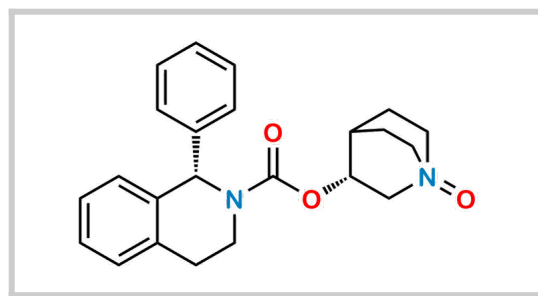
Alt. Name : Solifenacin N-Oxide (EP)

CAT No. : KMS005021

CAS No. : 180272-28-0

Molecular Formula : C₂₃H₂₆N₂O₃

Molecular Weight : 378.5



Analytical Information

Batch No. : S005021-114-361

Description : Off White Solid

HPLC Purity : 99.12 %

Weight Loss By TGA : 1.12 %

% Potency : 98.01 %

Solubility : ACN

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 = $[100 - 1.12(\text{Weight Loss By TGA})] \times [99.12(\text{HPLC Purity})]/100 = 98.01 \%$

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		29/05/2026
Reviewed & Approved By	Quality Control	Jatin Patel		29/05/2026

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