

CERTIFICATE OF ANALYSIS

(Certificate No. KMS005017-01)

Release Date: 27/10/2023

Re-test Date: 26/10/2026

Solifenacin EP Impurity F

Identification

Chemical Name :

(3S)-1-Azabicyclo[2.2.2]octan-3-yl (1R)-1-phenyl-3,4-dihydroisoquinoline-2(1H)-carboxylate (as per EP)

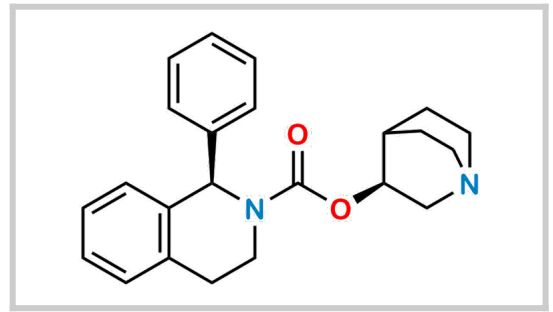
Alt. Name : Solifenacin (1R,3S)-Isomer

CAT No. : KMS005017

CAS No. : 774517-20-3

Molecular Formula : C₂₃H₂₆N₂O₂

Molecular Weight : 362.5



Analytical Information

Batch No. : Impurity-F R,S

Description : White Solid

HPLC Purity : 99.52 %

Weight Loss By TGA : 0.10 %

% Potency : 99.42 %

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 - 0.10(Weight Loss By TGA)] x [99.52(HPLC Purity)]/100 = 99.42 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		19/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		19/02/2025

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