

CERTIFICATE OF ANALYSIS

(Certificate No. KMS005014-01)

Release Date: 20/05/2026

Re-test Date: 19/05/2029

SOLIFENACIN SUCCINATE IMPURITY-C

Identification

Chemical Name :

Bis[(1S)-1-phenyl-3,4-dihydroisoquinolin-2(1H)-yl]methanone (as per EP)

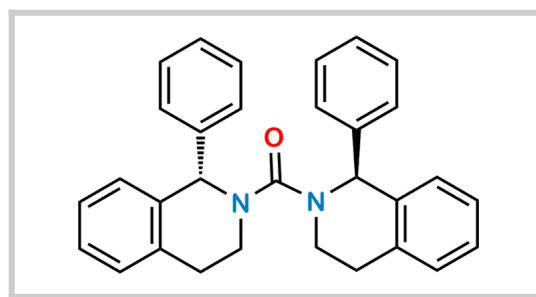
Alt. Name : Solifenacin (S,S) Methanone Impurity

CAT No. : KMS005014

CAS No. : 1534326-81-2

Molecular Formula : C₃₁H₂₈N₂O

Molecular Weight : 444.6



Analytical Information

Batch No. : S005014-114-331

Description : Off White Solid

HPLC Purity : 94.52 %

Weight Loss By TGA : 1.24 %

% Potency : 93.35 %

Solubility : ACN : Water

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 - 1.24(Weight Loss By TGA)] x [94.52(HPLC Purity)]/100 = 93.35 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		20/05/2026
Reviewed & Approved By	Quality Control	Jatin Patel		20/05/2026

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