

CERTIFICATE OF ANALYSIS

(Certificate No. KMS005015-01)

Release Date: 20/05/2026

Re-test Date: 19/05/2029

SOLIFENACIN SUCCINATE IMPURITY-D

Identification

Chemical Name :

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

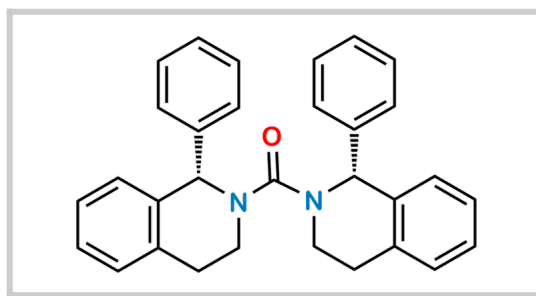
Alt. Name : Solifenacin (R,S) Methanone Impurity

CAT No. : KMS005015

CAS No. : 2216750-52-4

Molecular Formula : C₃₁H₂₈N₂O

Molecular Weight : 444.6



Analytical Information

Batch No. : S005015-114-332

Description : Off White Solid

HPLC Purity : 99.26 %

Weight Loss By TGA : 1.77 %

% Potency : 97.5 %

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 = $[100 - 1.77(\text{Weight Loss By TGA})] \times [99.26(\text{HPLC Purity})]/100 = 97.5 \%$

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