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)

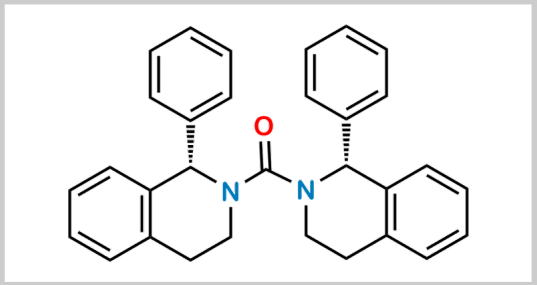
Alt. Name : Solifenacin (R,S) Methanone Impurity

CAT No. : KMS005015

CAS No. : 2216750-52-4

Molecular Formula : C31H28N2O

Molecular Weight : 444.6



Analytical Information

Batch No.	: S005015-114-332	**Solubility**	: THF
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 99.26 %	**IR**	: Confirm
Weight Loss By TGA	: 1.77 %	**1H NMR**	: Confirm
% Potency	: 97.5 %		

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(Weight Loss By TGA)] x [99.26(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, 1HNMR, IR and TGA