CERTIFICATE OF ANALYSIS

(Certificate No. KMS005013-02)

Release Date: 17/05/2026 **Re-test Date:** 16/05/2029

Solifenacin EP Impurity B

Identification

Chemical Name :
Propan-2-yl (1S)-1-phenyl-3,4-dihydroisoquinoline-2(1H)-carboxylate (as per EP)

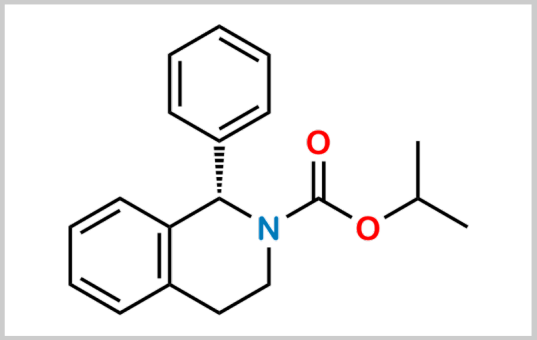
Alt. Name : Solifenacin Isopropyl Ester Impurity

CAT No. : KMS005013

CAS No. : 1353274-25-5

Molecular Formula : C19H21NO2

Molecular Weight : 295.4



Analytical Information

Batch No.	: S005013-114-323	**Solubility**	: ACN
Description	: Light Yellow Thick Syrup	**Mass**	: Confirm
HPLC Purity	: 99.75 %	**IR**	: Confirm
Weight Loss By TGA	: 2.12 %	**1H NMR**	: Confirm
% Potency	: 97.64 %		

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 - 2.12(Weight Loss By TGA)] x [99.75(HPLC Purity)]/100 = 97.64 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		17/05/2026
Reviewed & Approved By	Quality Control	Jatin Patel		17/05/2026

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