

# 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)

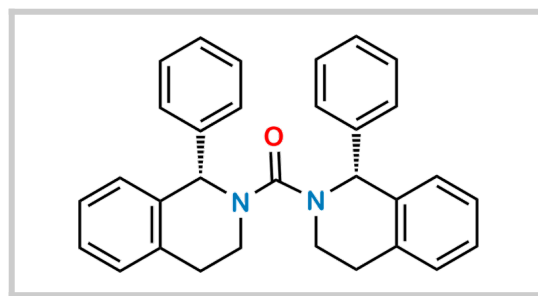
**Alt. Name** : Solifenacin (R,S) Methanone Impurity

**CAT No.** : KMS005015

**CAS No.** : 2216750-52-4

**Molecular Formula** : C<sub>31</sub>H<sub>28</sub>N<sub>2</sub>O

**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

**<sup>1</sup>H 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, <sup>1</sup>H NMR, IR and TGA