

# CERTIFICATE OF ANALYSIS

(Certificate No. KMS005021-01)

Release Date: 30/12/2023

Re-test Date: 29/12/2026

## Solifenacin N-Oxide

### Identification

**Chemical Name :**

(3R)-3-[[[(1S)-1-Phenyl-3,4-dihydroisoquinoline-2(1H)-carbonyl]oxy]-1-azabicyclo[2.2.2]octane 1-oxide (as per EP)

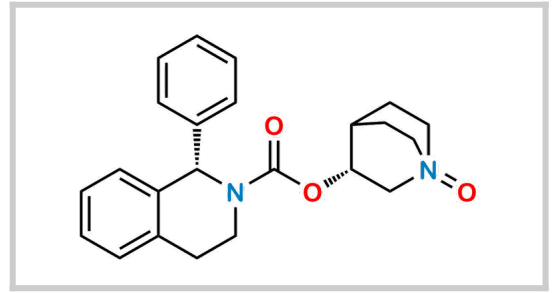
**Alt. Name** : Solifenacin N-Oxide (EP)

**CAT No.** : KMS005021

**CAS No.** : 180272-28-0

**Molecular Formula** : C<sub>23</sub>H<sub>26</sub>N<sub>2</sub>O<sub>3</sub>

**Molecular Weight** : 378.5



### Analytical Information

**Batch No.** : SOL-N-OXIDE-073-009

**Description** : Off White Solid

**HPLC Purity** : 94.71 %

**Weight Loss By TGA** : 0.92 %

**% Potency** : 93.84 %

**Solubility** : Acetonitrile

**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 - 0.92(Weight Loss By TGA)] x [94.71(HPLC Purity)]/100 = 93.84 %

Remarks : COA Re-generated on 06.01.2025

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		06/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		06/01/2025

**Attachments** : COA, HPLC, MASS, <sup>1</sup>H NMR, IR and TGA