

CERTIFICATE OF ANALYSIS

(Certificate No. KMS005001-01)

Release Date: 26/03/2024

Re-test Date: 25/03/2027

Solifenacin EP Impurity E

Identification

Chemical Name :
(R)-quinuclidin-3-ol

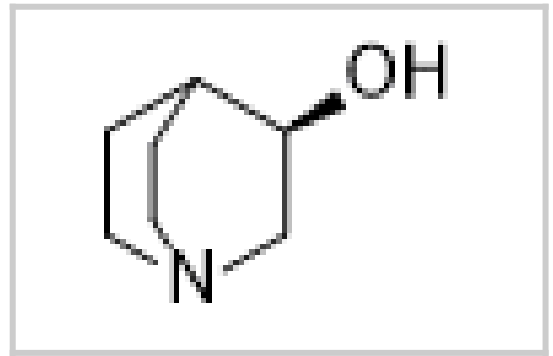
Alt. Name : 3-quinuclidinol

CAT No. : KMS005001

CAS No. : 25333-42-0

Molecular Formula : C₇H₁₃NO

Molecular Weight : 127.18



Analytical Information

Batch No. : SOL-EPE-073-139

Description : Light Yellow Solid

GC Purity : 92.78 %

Weight Loss By TGA : 0.53 %

% Potency : 92.29 %

Solubility : Methanol

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 - 0.53(Weight Loss By TGA)] x [92.78(GC Purity)]/100 = 92.29 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		26/03/2024
Reviewed & Approved By	Quality Control	Jatin Patel		26/03/2024

Attachments : COA, GC, MASS, ¹H NMR, IR and TGA