

CERTIFICATE OF ANALYSIS

(Certificate No. KMQ001042-01)

Release Date: 23/01/2026

Re-test Date: 22/01/2029

Quetiapine EP Impurity H

Identification

Chemical Name :

2-[2-[4-(Dibenzo[b,f][1,4]thiazepin-11-yl)-1-oxidopiperazin-1-yl]ethoxy]ethanol (as per EP)

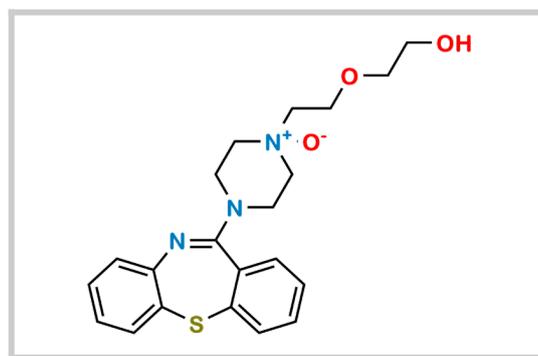
Alt. Name : Quetiapine N-Oxide ; Quetiapine USP
Related Compound H

CAT No. : KMQ001042

CAS No. : 1076199-40-0

Molecular Formula : C₂₁H₂₅N₃O₃S

Molecular Weight : 399.5



Analytical Information

Batch No. : Q001042-114-112

Description : White solid

HPLC Purity : 98.92 %

Weight Loss By TGA : 4.59 %

% Potency : 94.38 %

Solubility : ACN

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 - 4.59(Weight Loss By TGA)] x [98.92(HPLC Purity)]/100 = 94.38 %

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 18/02/2026 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 18/02/2026 |

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