

CERTIFICATE OF ANALYSIS

(Certificate No. KMQ001049-03)

Release Date: 27/02/2026

Re-test Date: 26/02/2029

Quetiapine EP Impurity P

Identification

Chemical Name :

11-(4-Ethylpiperazin-1-yl)dibenzo[b,f][1,4]thiazepine (as per EP)

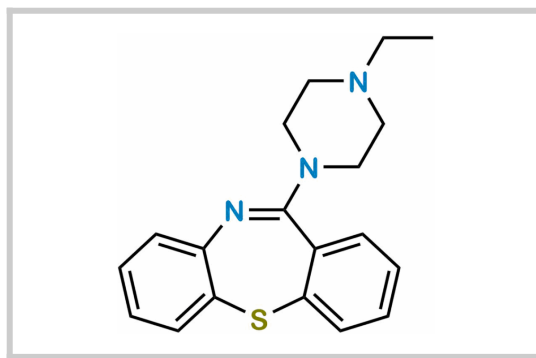
Alt. Name : N-Ethyl Quetiapine (USP)

CAT No. : KMQ001049

CAS No. : 1011758-03-4

Molecular Formula : C₁₉H₂₁N₃S

Molecular Weight : 323.5



Analytical Information

Batch No. : Q001049-114-183

Description : Colorless Thick Syrup

HPLC Purity : 99.26 %

Weight Loss By TGA : 1.14 %

% Potency : 98.13 %

Solubility : ACN : WATER

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

¹³C 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 - 1.14(Weight Loss By TGA)] x [99.26(HPLC Purity)]/100 = 98.13 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		27/02/2026
Reviewed & Approved By	Quality Control	Jatin Patel		27/02/2026

Attachments : COA, HPLC, MASS, ¹H NMR, ¹³C NMR, IR and TGA