

CERTIFICATE OF ANALYSIS

(Certificate No. KMQ001003-01)

Release Date: 08/02/2024

Re-test Date: 07/02/2027

Quetiapine Related Compound B

Identification

Chemical Name :

11-(piperazin-1-yl)dibenzo[b,f][1,4]thiazepine dihydrochloride

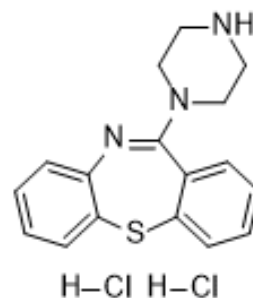
Alt. Name : Quetiapine EP Impurity B, N-Desalkyl
Quetiapine

CAT No. : KMQ001003

CAS No. : 111974-74-4

Molecular Formula : C₁₇H₁₇N₃S : 2(HCl)

Molecular Weight : 295.4 : 2(36.5)



Analytical Information

Batch No. : QUE-RCB-073-070

Solubility : ACN

Description : Off White Solid

Mass : Confirm

HPLC Purity : 99.98 %

IR : Confirm

Weight Loss By TGA : 3.82 %

¹H NMR : Confirm

% Potency : 96.16 %

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 - 3.82(Weight Loss By TGA)] x [99.98(HPLC Purity)]/100 = 96.16 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		01/10/2024
Reviewed & Approved By	Quality Control	Jatin Patel		01/10/2024

Attachments : COA, HPLC, MASS, ¹HNMR, IR and TGA