

CERTIFICATE OF ANALYSIS

(Certificate No. KMQ001038-01)

Release Date: 09/01/2025

Re-test Date: 08/01/2028

Quetiapine EP Impurity D

Identification

Chemical Name :

11,11'-(Piperazine-1,4-diyl)bis(dibenzo[b,f][1,4]thiazepine) (as per EP)

Alt. Name

: Quetiapine Dimer Impurity ;
Quetiapine Bis(dibenzothiazepinyl)
piperazine Impurity (USP)

CAT No.

: KMQ001038

CAS No.

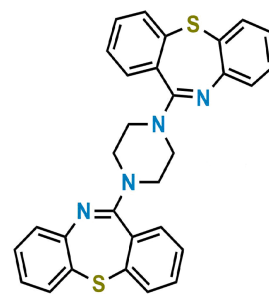
: 945668-94-0

Molecular Formula

: C30H24N4S2

Molecular Weight

: 504.7



Analytical Information

Batch No.

: Q001038-091-130

Solubility

: THF

Description

: White Solid

Mass

: Confirm

HPLC Purity

: 99.73 %

IR

: Confirm

Weight Loss By TGA

: 0.41 %

¹H NMR

: Confirm

% Potency

: 99.32 %

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 - 0.41(Weight Loss By TGA)] x [99.73(HPLC Purity)]/100 = 99.32 %

Recommendation

: Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		08/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		08/05/2025

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