

CERTIFICATE OF ANALYSIS

(Certificate No. KMC017008-01)

Release Date: 12/12/2024

Re-test Date: 11/12/2027

Clozapine Impurity A

Identification

Chemical Name :

8-Chloro-11-(piperazin-1-yl)-5H-dibenzo[b,e][1,4]diazepine (as per EP)

Alt. Name

: Clozapine impurity A (USP) ;
Clozapine EP Impurity C (as per EP)

CAT No.

: KMC017008

CAS No.

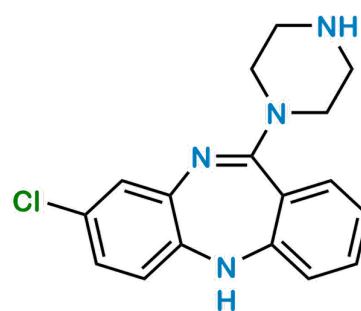
: 6104-71-8

Molecular Formula

: C₁₇H₁₇ClN₄

Molecular Weight

: 312.8



Analytical Information

Batch No.

: C017008-091-082

Solubility

: Acetonitrile

Description

: Yellow Solid

Mass

: Confirm

HPLC Purity

: 99.23 %

IR

: Confirm

Weight Loss By TGA

: 3.93 %

¹H NMR

: Confirm

% Potency

: 95.33 %

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 - 3.93(Weight Loss By TGA)] x [99.23(HPLC Purity)]/100 = 95.33 %

Recommendation

: Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		12/12/2024
Reviewed & Approved By	Quality Control	Jatin Patel		12/12/2024

Attachments : COA, HPLC, MASS, ¹HNMR, ¹³CNMR, IR and TGA