

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)

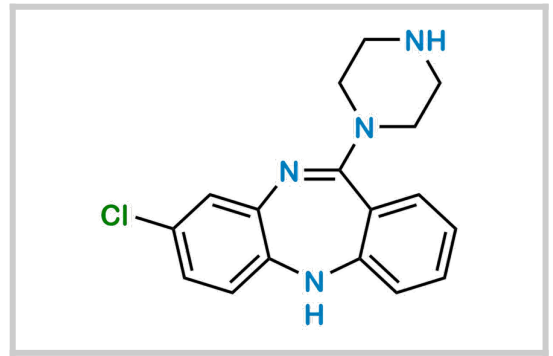
Alt. Name : Clozapine impurity A (USP) ;
Clozapine EP Impurity C (as per EP)

CAT No. : KMC017008

CAS No. : 6104-71-8

Molecular Formula : C₁₇H₁₇ClN₄

Molecular Weight : 312.8



Analytical Information

Batch No. : C017008-091-082

Description : Yellow Solid

HPLC Purity : 99.23 %

Weight Loss By TGA : 3.93 %

% Potency : 95.33 %

Solubility : Acetonitrile

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 - 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, ¹H NMR, ¹³C NMR, IR and TGA