

CERTIFICATE OF ANALYSIS

(Certificate No. KMC017007-01)

Release Date: 12/12/2024

Re-test Date: 11/12/2027

Clozapine Impurity D

Identification

Chemical Name :

11,11'-(piperazine-1,4-diyl)bis(8-chloro-5H-dibenzo[b,e][1,4]diazepine) (as per EP)

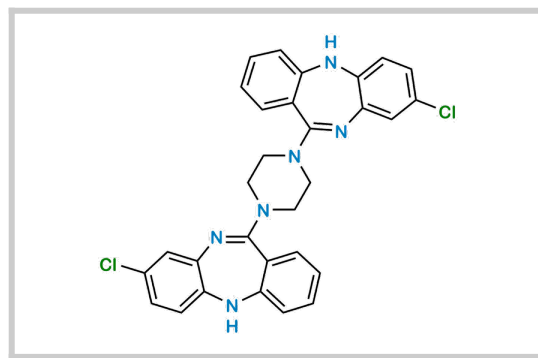
Alt. Name : Clozapine impurity D (USP) ;
Clozapine EP Impurity B (as per EP)

CAT No. : KMC017007

CAS No. : 263366-81-0

Molecular Formula : C₃₀H₂₄Cl₂N₆

Molecular Weight : 539.5



Analytical Information

Batch No. : C017007-091-081

Description : Off White Solid

HPLC Purity : 98.73 %

Weight Loss By TGA : 0.64 %

% Potency : 98.1 %

Solubility : DMSO

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 - 0.64(Weight Loss By TGA)] x [98.73(HPLC Purity)]/100 = 98.1 %

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