

CERTIFICATE OF ANALYSIS

(Certificate No. KMC017009-01)

Release Date: 12/12/2024

Re-test Date: 11/12/2027

Clozapine Impurity B

Identification

Chemical Name :

1-[2-[(2-Amino-4-chlorophenyl)amino]benzoyl]-4-methylpiperazine (as per EP)

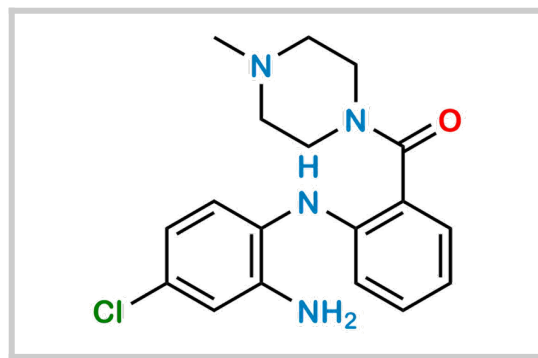
Alt. Name : Clozapine impurity B (USP) ;
Clozapine EP Impurity D (as per EP)

CAT No. : KMC017009

CAS No. : 65514-71-8

Molecular Formula : C₁₈H₂₁ClN₄O

Molecular Weight : 344.8



Analytical Information

Batch No. : C017009-091-080

Description : Off White Solid

HPLC Purity : 99.06 %

Weight Loss By TGA : 1.70 %

% Potency : 97.38 %

Solubility : ACN : Water (1:1)

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 - 1.70(Weight Loss By TGA)] x [99.06(HPLC Purity)]/100 = 97.38 %

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