

# 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)

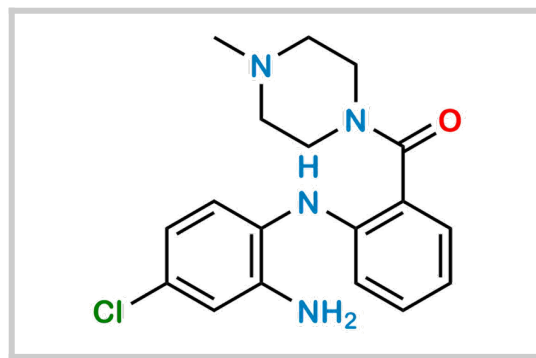
**Alt. Name** : Clozapine impurity B (USP) ;  
Clozapine EP Impurity D (as per EP)

**CAT No.** : KMC017009

**CAS No.** : 65514-71-8

**Molecular Formula** : C<sub>18</sub>H<sub>21</sub>ClN<sub>4</sub>O

**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

**<sup>1</sup>H NMR** : Confirm

**<sup>13</sup>C 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, <sup>1</sup>H NMR, <sup>13</sup>C NMR, IR and TGA