

# 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.**

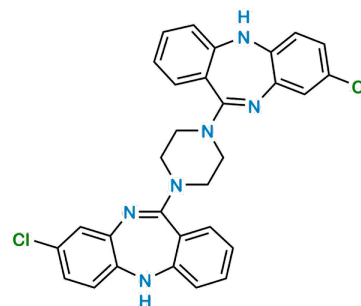
: 263366-81-0

**Molecular Formula**

: C<sub>30</sub>H<sub>24</sub>Cl<sub>2</sub>N<sub>6</sub>

**Molecular Weight**

: 539.5



### Analytical Information

**Batch No.**

: C017007-091-081

**Solubility**

: DMSO

**Description**

: Off White Solid

**Mass**

: Confirm

**HPLC Purity**

: 98.73 %

**IR**

: Confirm

**Weight Loss By TGA**

: 0.64 %

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

: Confirm

**% Potency**

: 98.1 %

**<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 - 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, <sup>1</sup>HNMR, <sup>13</sup>CNMR, IR and TGA