

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.

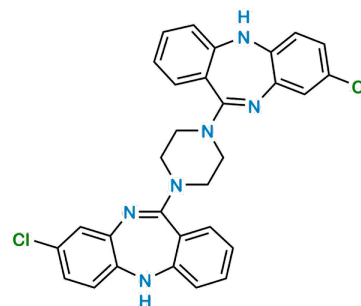
: 263366-81-0

Molecular Formula

: C₃₀H₂₄Cl₂N₆

Molecular Weight

: 539.5



Analytical Information

Batch No.

: C017007-091-081

Solubility

: DMSO

Description

: Off White Solid

Mass

: Confirm

HPLC Purity

: 98.73 %

IR

: Confirm

Weight Loss By TGA

: 0.64 %

¹H NMR

: Confirm

% Potency

: 98.1 %

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, ¹HNMR, ¹³CNMR, IR and TGA