

CERTIFICATE OF ANALYSIS

(Certificate No. KMC017006-01)

Release Date: 12/12/2024

Re-test Date: 11/12/2027

8-Chloro-5,10-dihydrodibenzo[b,e][1,4]diazepin-11-one

Identification

Chemical Name :

8-chloro-5,10-dihydro-11H-dibenzo[b,e][1,4]diazepin-11-one (as per EP)

Alt. Name

: Clozapine impurity C (USP) ;
Clozapine impurity-A (As per IP) ;
Clozapine EP Impurity A (As per EP)

CAT No.

: KMC017006

CAS No.

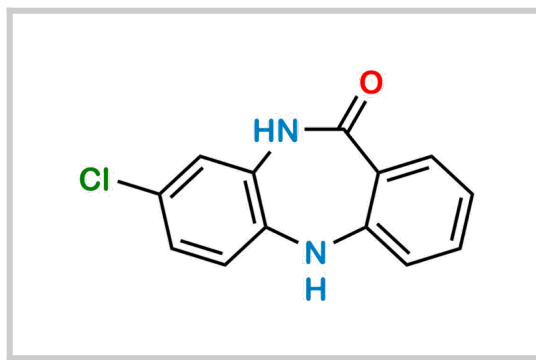
: 50892-62-1

Molecular Formula

: C₁₃H₉ClN₂O

Molecular Weight

: 244.7



Analytical Information

Batch No.

: C017006-091-078

Solubility

: Methanol

Description

: Grey Solid

Mass

: Confirm

HPLC Purity

: 99.82 %

IR

: Confirm

Weight Loss By TGA

: 0.13 %

¹H NMR

: Confirm

% Potency

: 99.69 %

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 - 0.13(Weight Loss By TGA)] x [99.82(HPLC Purity)]/100 = 99.69 %

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