

CERTIFICATE OF ANALYSIS

(Certificate No. KMT003006-01)

Release Date: 18/09/2023

Re-test Date: 17/09/2026

Temazepam EP impurity F

Identification

Chemical Name :

(5RS)-7-chloro-1-methyl-5-phenyl-4,5-dihydro-1H-1,4-benzodiazepine-2,3-dione

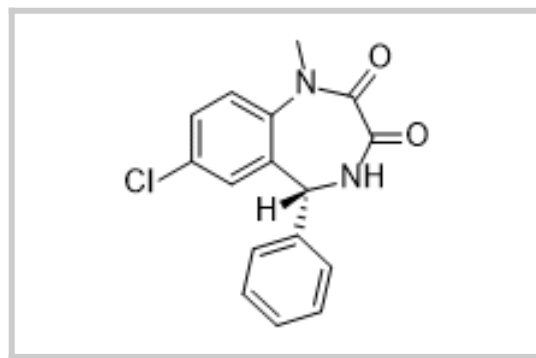
Alt. Name : Temazepam USP Related Compound F

CAT No. : KMT003006

CAS No. : 3294-96-0

Molecular Formula : C₁₆H₁₃ClN₂O₂

Molecular Weight : 300.74



Analytical Information

Batch No. : TEM-IMP-F-045-272

Solubility : ACN

Description : Yellow Solid

Mass : Confirm

HPLC Purity : 97.25 %

IR : Confirm

Weight Loss By TGA : 0.19 %

¹H NMR : Confirm

% Potency : 97.07 %

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 - 0.19(Weight Loss By TGA)] x [97.25(HPLC Purity)]/100 = 97.07 %

Remarks : COA Re-generated on 25.05.2024

Recommendation : Released

| | Department | Name | Signature | Date |
|-----------------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 25/05/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 25/05/2024 |

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA