

CERTIFICATE OF ANALYSIS

(Certificate No. KMC020001-01)

Release Date: 06/05/2025

Re-test Date: 05/05/2028

N-Nitroso Cyclophosphamide EP Impurity D

Identification

Chemical Name :

3-(2-chloroethyl)-2-hydroxy-6-nitroso-1,3,6,2-oxadiazaphosphonane 2-oxide (Mixture of E/Z Isomer)

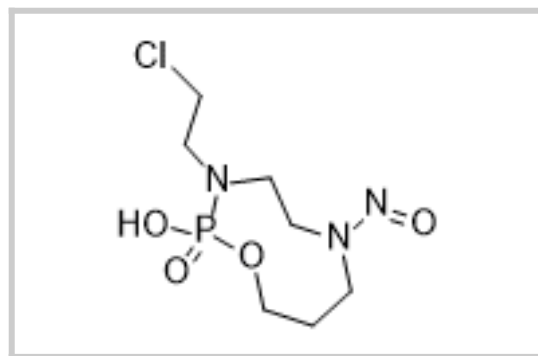
Alt. Name : N-Nitroso Cyclophosphamide USP
Related compound B

CAT No. : KMC020001

CAS No. : Not Available

Molecular Formula : C₇H₁₅ClN₃O₄P

Molecular Weight : 271.64



Analytical Information

Batch No. : CYC-EPD-NO-073-147

Solubility : Water

Description : Off white Hygroscopic Solid

Mass : Confirm

HPLC Purity : 96.23 %

IR : Confirm

Weight Loss By TGA : 2.24 %

¹H NMR : Confirm

% Potency : 94.07 %

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 - 2.24(Weight Loss By TGA)] x [96.23(HPLC Purity)]/100 = 94.07 %

-Mixture of Isomers

-Re-purified and re-tested on 06.05.2025

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 09/05/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 09/05/2025 |

Attachments : COA, HPLC, MASS, ¹HNMR, ¹³CNMR, IR and TGA