

# CERTIFICATE OF ANALYSIS

(Certificate No. KMC020001-01)

Release Date: 20/04/2024

Re-test Date: 19/04/2027

## 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)

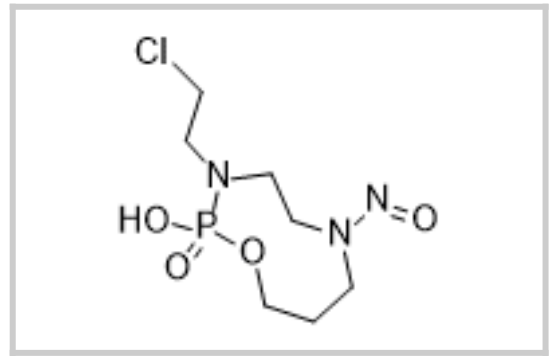
**Alt. Name** : N-Nitroso Cyclophosphamide USP  
Related compound B

**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** : Light Yellow Thick Syrup

**Mass** : Confirm

**HPLC Purity** : 98.35 %

**IR** : Confirm

**Weight Loss By TGA** : 6.88 %

**1H NMR** : Confirm

**% Potency** : 91.58 %

**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** =  $[100 - 6.88(\text{Weight Loss By TGA})] \times [98.35(\text{HPLC Purity})]/100 = 91.58 \%$   
-Mixture of Isomers

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		20/04/2024
Reviewed & Approved By	Quality Control	Jatin Patel		20/04/2024

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