

# 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)

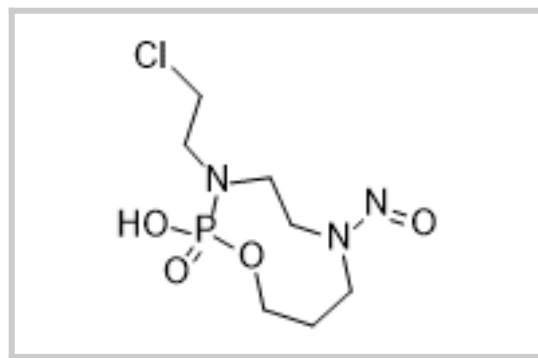
**Alt. Name** : N-Nitroso Cyclophosphamide USP  
Related compound B

**CAT No.** : KMC020001

**CAS No.** : Not Available

**Molecular Formula** : C<sub>7</sub>H<sub>15</sub>ClN<sub>3</sub>O<sub>4</sub>P

**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 %

**<sup>1</sup>H NMR** : Confirm

**% Potency** : 94.07 %

**<sup>13</sup>C 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, <sup>1</sup>HNMR, <sup>13</sup>CNMR, IR and TGA