

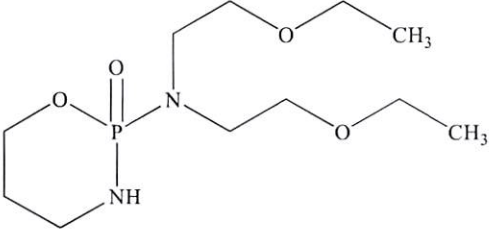
Certificate of Analysis

Certificate No.: 20220728002


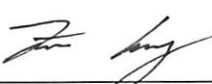
Date: July 28, 2022

Retest date: July 25, 2025

Compound Name: Cyclophosphamide Impurity 21	
Synonyms:	2-(bis(2-ethoxyethyl)amino)-1,3,2-oxazaphosphinane 2-oxide
TLC Catalogue Number:	C-10237
CAS Number:	N/A
Molecular Weight:	280.30
Molecular Formula:	C ₁₁ H ₂₅ N ₂ O ₄ P
Source:	TLC Pharmaceutical Standards
Source Lot No.:	4011-024A7
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO



Test Description	Specifications	Results
Visual Description	Colorless liquid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	100.0%
Impurity (HPLC)	N/A	
Water Content (KF)	N/A	2.5%
Residual Solvents (NMR)	0.1% methanol	
Assay (%)	Not less than 90.0%	97.4%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		07 / 29 / 2022
Approved by:	Quality Assurance		07 / 29 / 2022

Attachments: HPLC, IR, MS and NMR spectra.