

**AARTI INDUSTRIES LIMITED**

Factory : Unit - IV, Plot No. E-50, MIDC, Tarapur,
Taluka & District- Palghar, Pin - 401506. Maharashtra, INDIA.
Tel.: +91 8983035452, 8983065452, Telefax : (02525) 661092

CERTIFICATE OF ANALYSIS CYCLOPHOSPHAMIDE USP

Format No. : QA/FM-235/00

Batch No.	: CY-19003	Date of Mfg.	: NOV-2019
AR. No.	: FG/RN/0011/20	Date of Exp.	: OCT-2024
Batch Qty.	: 15.197 Kg	Date of Release	: 11/02/21

Sr. No.	TESTS	RESULTS	SPECIFICATION
1.	Description	White crystalline powder, liquefies upon loss of its water of crystallization	White crystalline powder. Liquefies upon loss of its water of crystallization.
2.	Solubility	Complies	Soluble in water and in alcohol .
3.	Identification A) By IR	Complies	The Infrared spectrum of test sample should be concordant with similar preparation of that of Cyclophosphamide WS.
	B) By HPLC	Complies	The retention time of the major peak in the chromatogram of the test preparation corresponds to that of the standard preparation as obtained in the assay.
4.	A) Limit of propanolamine (By HPTLC)	Complies	The spot of propanolamine from the sample solution is not more intense than the spot of propanolamine from the standard solution (0.025%)
	B) Limit of Degradation products (By TLC)	Complies	Cyclophosphamide Related : Not more than 0.06% compound A
		Complies	Cyclophosphamide Related: Not more than 0.06% compound B
		Complies	Cyclophosphamide Related: Not more than 0.06% compound C
		Complies	Cyclophosphamide Related: Not more than 0.06% compound D
		Complies	Any unspecified impurity : Not more than 0.06%
5.	Limit of chloride (By potentiometry)	0.0065 %	Not more than 0.033%
6.	Limit of Phosphates	Complies	Any color from the test solution is not more intense than that from the standard solution. (Not more than 0.01%)
7.	pH	5.52	Between 3.9 - 7.1
8.	Water content (By KF)	6.24 %	Between 5.7% - 6.8 %
9.	Assay (By HPLC)	99.71 %	Not less than 97.0 % w/w and Not more than 103.0 % on anhydrous basis

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HEAD OFFICE :

71, Udyog Kshetra, 2nd Floor, Mulund Goregaon Link Road, Mulund (W), Mumbai - 400 080. INDIA
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Regd. Office : Plot No. 801/23, G.I.D.C. Estate, Phase - III, Vapi-396195, Dist- Valsad, Gujarat, INDIA.
Website : www.aarti-industries.com • CIN: L24110GJ1984PLC007301

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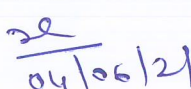
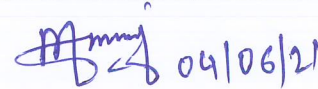
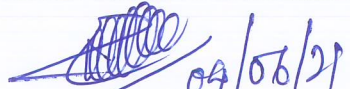
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10.	Residual solvent (By HSGC)	7 ppm	Methanol : Not more than 3000 ppm
		Not detected	Dichloromethane : Not more than 600 ppm
		6 ppm	Di-isopropyl ether : Not more than 5000 ppm
		1 ppm	Methyl Tert-butyl ether : Not more than 5000 ppm
11.	Triethylamine content (By HSGC)	Not detected	Not more than 320 ppm
12.	Related Substances (By HPLC)	Not detected	Related compound A : Not more than 0.06%
		0.01%	Related compound B : Not more than 0.06%
		Not detected	Related compound C : Not more than 0.06%
		Not detected	Related compound D : Not more than 0.06%
		Not detected	3 Amino 1-Propanol : Not more than 0.06%
		0.01%	Any other unknown impurity : Not more than 0.06%
		0.02%	Total impurities : Not more than 0.50%

Remark: The material complies as per USP and above specification.

Prepared By	Checked By	Approved By
 04/06/21	 04/06/21	 04/06/21
Executive/Designee Quality Assurance	Manager/Designee Quality Assurance	Head Quality Assurance/ Quality Control/Designee

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