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 Ph.Eur

Format No. : QA/FM-235/00

Batch No.	: CY-19504	**Date of Mfg.**	: JAN-2019
AR. No.	: RT/FG/0032/21	**Retest Date**	: DEC-2022
Batch Qty.	: 14.448 Kg	**Date of Release**	: 19/01/22

Sr. No	TESTS	RESULTS	SPECIFICATION
1.	Description	A white crystalline powder	A white or almost white crystalline powder.
2.	Solubility	Complies	Soluble in water, freely soluble in alcohol.
3.	Identification First identification B Second identification A,C,D A. Melting point	49.9 °C	Between 49.0 °C and 53.0 °C
	B.By IR Spectrum	Complies	The Infrared Spectrum of test Sample should be concordant with similar preparation of that of Cyclophosphamide WS/CRS.
	C. By TLC	Complies	The Principal spot in the chromatogram obtained with test solution (b) is similar in position, colour and size to the principle spot in the chromatogram obtained with reference solution(a).
	D. Chloride test	Complies	To comply the test
4.	Appearance of solution	Complies	Solution S is clear and not more intensely coloured than reference solution Y_6.
5.	pH	5.08	Between 4.0 and 6.0
6.	Related substances (By TLC)	Complies	Any spot in the chromatogram obtained with test solution (a), apart from the principle spot, is not more intense than the spot in the chromatogram obtained with reference solution(b) (1.0%).
7.	Chlorides	Complies	Not more than 330 ppm
8.	Phosphates	Complies	Not more than 100 ppm
9.	Water content (By KF)	6.36 %	Between 6.0 % and 7.0 % w/w.
10.	Assay (By Titrimetry)	100.31%	Not less than 98.0 % w/w and Not more than 102.0 % on anhydrous basis
11.	Related Substances (By HPLC)	Below Detection Limit	Related compound A : Not more than 0.06%
		0.01%	Related compound B : Not more than 0.06%
		Below Detection Limit	Related compound C : Not more than 0.06%
		Not Detected	Related compound D : Not more than 0.06%
		Below Detection Limit	3 Amino 1-Propanol : Not more than 0.06%
		0.01%	Any other unknown impurity : Not more than 0.06%
		0.04%	Total impurities : Not more than 0.50%

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Sr. No	TESTS	RESULTS	SPECIFICATION
12.	Residual solvent (By HSGC)	7 ppm	Methanol : Not more than 3000 ppm
		32 ppm	Dichloromethane : Not more than 600 ppm
		Not detected	Di-isopropyl ether : Not more than 5000 ppm
		119 ppm	Methyl Tert Butyl Ether : Not more than 5000 ppm
13.	Triethylamine content (By HSGC)	Below Detection Limit	Not more than 320 ppm
14.	Microbial limits **1.Total Viable Count** (Microbial Enumeration test) 1.1) Total Aerobic Microbial count (TAMC) 1.2) Total combined yeast and mould count (TYMC) **2. Test for specified Microorganism** 2.1) Bile tolerant gram negative bacteria 2.1.1) Test for Absence 2.1.2) Quantitative test 2.2) Escherichia coli 2.3)Salmonella 2.4) Pseudomonas aeruginosa 2.5) Staphylococccus aureus 2.6) Candida albicans	 < 10 CFU / g < 10 CFU / g Absent /g < 10 CFU / g Absent /g Absent /10 g Absent /g Absent /g Absent /g	 NMT 1000 CFU / g NMT 100 CFU / g Absent /g NMT 10 CFU / g Absent /g Absent /10 g Absent /g Absent /g Absent /g
15.	Bacterial Endotoxin	Complies	Not more than 0.0625 EU/mg

Remark: The material Complies as per Ph.Eur.and above specification.

Prepared By	Checked By	Approved By
13/05/22	13/05/22	13/05/22
Executive/Designee Quality Assurance	Manager/Designee Quality Assurance	Head Quality Assurance/ Quality Control/Designee

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