Lot: 0021220

Emcure

Certificate Of Analysis			
Name of material	CYCLOPHOSPHAMIDE Ph.Eur.		
Manufactured by	Emcure Pharmaceuticals Limited		
A.R. No.	40000725961	Release date	27 AUG 2020
Batch No.	5CYO220001	Quantity	13.680 Kg
Mfg. date	02 AUG 2020	Expiry date	01 AUG 2025

CHARACTERS

Sr. No.	Tests	Acceptance Criteria / Limit	Results
01	Appearance	A white or almost white, crystalline powder.	White crystalline powder.
02	Solubility	Soluble in water, freely soluble in alcohol.	Soluble in water, freely soluble in alcohol.

RELEASE SPECIFICATION

Sr. No.	Tests	Acceptance Criteria / Limit	Results
03	Identification First identification: B Second identification: A, C, D A)By Melting point	The difference between the melting points (which are about 51°C) is not greater than 2°C.	50°C
	B) By IR	The infrared absorption spectrum of the sample preparation exhibits maxima at the same wavenumbers as that of similar preparation of corresponding standard.	Meets the requirement.
	C) By TLC	The principal spot in the chromatogram obtained with sample solution (b) is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a) as obtained in related substances by TLC.	Meets the requirement.

Compiled by :	Checked by :	Approved by :
Date : 27.10.2020	Date : 27 Oct 2020	Date : 27 Oct 2020
Operating Personnel QC	Head QC (Designee)	Head QA (Designee)

Emcure Pharmaceuticals Limited

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Phone Nos. : +91 20 30610000, 27120084 Fax No. : 91 - 20 - 30610111 E.Mail : corporate@emcure.co.in
CIN : U24231PN1981PLC024251

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Sr. No.	Tests	Acceptance Criteria / Limit	Results
	D) By Silver nitrate solution	Meets the requirements.	Meets the requirement.
04	Appearance of solution A) Clarity by visual method	Solution S is clear.	Meets the requirement.
	B) By color of solution	Solution S is not more intensely coloured than reference solution Y_6.	Meets the requirement.
05	pH	Between 4.0 and 6.0.	5.7
06	Related substances by TLC Any individual impurity	Not more than 1.0 percent.	Meets the requirement.
07	Chlorides	Not more than 330 ppm.	Meets the requirement.
08	Phosphates	Not more than 100 ppm.	Meets the requirement.
09	Water content by KF	Between 6.0 percent and 7.0 percent.	6.6% w/w
10	Assay by Titrimetry	Not less than 98.0 percent and not more than 102.0 percent calculated on anhydrous basis.	98.9% w/w

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Sr. No.	Tests	Acceptance Criteria / Limit	Results
11	Assay by HPLC	Not less than 97.0% w/w and not more than 103.0 % w/w of $C_7H_{15}Cl_2N_2O_2P$, calculated on the anhydrous basis.	99.4% w/w
12	Bacterial Endotoxin test	Not more than 0.20 EU/mg.	Meets the requirement
13	Microbiological examination a) Microbial enumeration tests i) Total aerobic microbial count (TAMC)	Not more than 100 cfu/g	00 cfu/g
	ii) Total combined yeasts and molds count (TYMC)	Not more than 10 cfu/g	00 cfu/g
	b) Tests for specified Micro-organisms i) *Bile Tolerant Gram Negative Bacteria*	Should be absent per g	Absent per g
	ii) *Escherichia coli*	Should be absent per g	Absent per g
	iii) *Salmonella*	Should be absent per 10 g	Absent per 10 g
	iv) *Pseudomonas aeruginosa*	Should be absent per g	Absent per g

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	v) *Staphylococcus aureus*	Should be absent per g	Absent per g
	vi) *Clostridia*	Should be absent per g	Absent per g
	vii) *Candida albicans*	Should be absent per g	Absent per g
In-house Specification:			
14	Residual solvents by GC-HS Method I Acetone	Not more than 5000 ppm	Not detected.
	Methanol	Not more than 3000 ppm	Not detected.
	Dichloromethane	Not more than 600 ppm	Not detected.
	Method II Triethylamine	Not more than 320 ppm	Below limit of quantitation
15	Related substances by HPLC Method I Impurity A	Not more than 0.05%	Not detected.
	Monochloro impurity	Not more than 0.05%	Below limit of quantitation
	Any other individual impurity	Not more than 0.05%	0.03%

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Sr. No.	Tests	Acceptance Criteria / Limit	Results
	Method II Impurity B	Not more than 0.05%	Not detected.
	Di-(2-chloroethyl) Phosphoramidic Dichloride	Not more than 0.05%	Not detected.
	Method III Monochloro open chain impurity	Not more than 0.05%	Below limit of quantitation
	Total impurities	Not more than 0.30%	0.03 %
16	Limit of degradation products (By TLC) Cyclophosphamide related compound A	Not more than 0.05%	Meets the requirement
	Cyclophosphamide related compound B	Not more than 0.05%	Meets the requirement
	Cyclophosphamide related compound C	Not more than 0.05%	Meets the requirement
	Cyclophosphamide related compound D	Not more than 0.05%	Meets the requirement
	Any individual unspecified impurity	Not more than 0.05%	Meets the requirement

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1.Limit of quantitation (LOQ) for Residual solvents by GC-HS Method -I are as below

a) Methanol = 100 ppm
b) Acetone = 39 ppm
c) Dichloromethane = 67 ppm

2.Limit of quantitation (LOQ) for Residual solvents by GC-HS Method -II is as below

a) Triethylamine = 48 ppm

3.Limit of quantitation (LOQ) for Related substances by HPLC Method –I are as below

a) Any unspecified impurity = 0.020%
b) Impurity-A = 0.021%
c) Monochloro impurity = 0.021%

4.Limit of quantitation (LOQ) for Related substances by HPLC Method –II are as below

a) Di-(2-chloroethyl) phosphoramidic dichloride = 0.018%
b) Impurity-B = 0.027%

5.Limit of quantitation (LOQ) for Related substances by HPLC Method –III are as below

a) Monochloro open chain impurity = 0.021%

Remark: The product complies as per specification number SC-DS-069/06.

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