Lote: 0021220

Emcure

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			Certificate Of Analysi	is			
Nam	e of material	CYCLOPH	OSPHAMIDE Ph.Eur.				
Man	ufactured by	Emcure P	harmaceuticals Limited		A SAMO		
A.R.	No.	40000725	961	Release	date	27 AUG 2020	
Batc	h No.	5CYO220	001	Quantity		13.680 Kg	
Mfg.	date	02 AUG 2	020	Expiry da	ate	01 AUG 2025	
			CHARACTERS				
Sr. No.	Test	ts	Acceptance Criteria /	Limit		Results	
01	Appearance		A white or almost white, cryst powder.	alline	Wh	ite crystalline powder.	
02	Solubility		Soluble in water, freely soluble	le in alcoh		Soluble in water, freely soluble in alcohol.	
			RELEASE SPECIFICATION	NC			
Sr. No.	Tests		Acceptance Criteria / Limit			Results	
03	Identification First identific Second ident A, C, D A)By Melting B) By IR C) By TLC	ification:	The difference between the new (which are about 51°C) is not 2°C. The infrared absorption spect sample preparation exhibits in the same wavenumbers as the preparation of corresponding. The principal spot in the chromotoal sample with sample solution similar in position, colour and principal spot in the chromato obtained with reference solut obtained in related substance.	trum of the maxima at nat of simil standard. matogram n (b) is I size to the ogram ion (a) as	ar Me	C ets the requirement. ets the requirement.	
Date	npiled by: Significant services in the services of the service	DCH-2023 Iel QC	Checked by: Date : 27 oct 2000 Head QC Designee	Da		by: A : 27 oct 2020 Designee	

Emcure Pharmaceuticals Limited

Registered Office: Emcure House, T-184, M.I.D.C., Bhosari, Pune 411 026. INDIA
Phone Nos.: +91 20 30610000, 27120084 Fax No.: 91 - 20 - 30610111 E.Mail: corporate@emcure.co.in
CIN: U24231PN1981PLC024251

Page No.: 2 of 6

			Certificate Of Analys	is		
Nam	e of material	CYCLOPHOSE	PHAMIDE Ph.Eur.			
Manufactured by Emcure Pharma		aceuticals Limited				
A.R.	No.	40000725961		Release date	е	27 AUG 2020
Batc	h No.	5CYO220001		Quantity		13.680 Kg
Mfg.	date	02 AUG 2020		Expiry date		01 AUG 2025
Sr. No.	Te	ests	Acceptance Criteri	a / Limit		Results
	D) By Silver n	itrate solution	Meets the requirements.		Mee	ts the requirement.
04	Appearance o	f solution				
	A) Clarity by v	risual 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	рН		Between 4.0 and 6.0.		5.7	
06	Related subst	ances by TLC		New York Control of the Control of t		
	Any individual	impurity	Not more than 1.0 percent.		Meets the requirement.	
07	Chlorides	and the second s	Not more than 330 ppm.		Meets the requirement.	
08	Phosphates		Not more than 100 ppm.		Meets the requirement.	
09	Water conten	t by KF	Between 6.0 percent and 7.0 percent.		6.6% w/w	
10	Assay by Titri	imetry	Not less than 98.0 percent and not more than 102.0 percent calculated on anhydrous basis.		98.9% w/w	

Compiled by:

Date : 2704200 Date : 2704200 Date : 2704200

Operating Personnel QC Head QC (Designee)

Approved by:
Date : 2704200 Head QA / Designee

Emcure Pharmaceuticals Limited

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			Certificate Of Analys	is				
Nam	e of material	CYCLOPHOSPHAMIDE Ph.Eur.						
Manufactured by		Emcure Pharmaceuticals Limited						
A.R.	No.	40000725961		Release da	te	27 AUG 2020		
Bato	h No.	5CYO220001		Quantity		13.680 Kg		
Mfg.	date	02 AUG 2020		Expiry date)	01 AUG 2025		
Sr. No.	Те	sts	Acceptance Criteria	a / Limit		Results		
11	Assay by HPL	.c	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. Not more than 0.20 EU/mg.			% w/w		
12	Bacterial End	otoxin test				Meets the requirement		
13	Microbiological examination a) Microbial enumeration tests i) Total aerobic microbial count (TAMC)		Not more than 100 cfu/g Not more than 10 cfu/g		00 cf			
	b) Tests for s Micro-orga i) Bile Tolerar Negative Ba	pecified nisms nt Gram acteria	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		Abse	ent per g		

Compiled by:	Checked by :	Approved by:
Date: 3700x2020	Date : 27 oct 2020	Date : 27 oct 20 20
Operating Personnel QC		Head QA / Designee

Emcure Pharmaceuticals Limited

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CIN: U24231PN1981PLC024251

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			Certificate Of Analys	sis			
Nam	e of material	CYCLOPHOSE	HAMIDE Ph.Eur.				
Man	ufactured by	Emcure Pharm	aceuticals Limited				
A.R.	No.	40000725961		Release o	late	27 AUG 2020	
Batc	h No.	5CYO220001		Quantity		13.680 Kg	
Mfg.	dạte	02 AUG 2020		Expiry da	te	01 AUG 2025	
Sr. No.	Te	sts	Acceptance Criteri	a / Limit		Results	
	v) Staphylococcus aureus		Should be absent per g		Abs	ent per g	
	vi) Clostridia		Should be absent per g	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Abs	ent per g	
	vii) Candida a	lbicans	Should be absent per g		Abs	Absent per g	
In-ho	ouse Specificat	ion:					
14	Residual solvents by GC-HS						
	Method I						
	Acetone		Not more than 5000 ppm		Not	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		Belo	Below limit of quantitation	
15	Related substances by						
	HPLC						
	Method I						
	Impurity A		Not more than 0.05%		Not	Not detected.	
	Monochloro impurity		Not more than 0.05%		Below limit of quantitation		
	Any other individual impurity		Not more than 0.05%		0.03	0.03%	

Checked by: 🔎 Compiled by: Approved by: 90 : 27 oct 2020 Date : 27042020 Date Date : 240ct 2020 Head QA / Designee

Operating Personnel QC Head QC (Designee)

Emcure Pharmaceuticals Limited

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CIN: U24231PN1981PLC024251

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			Certificate Of Analys	is		
Nam	e of material	CYCLOPHOSP	PHAMIDE Ph.Eur.			
Manufactured by		Emcure Pharma	aceuticals Limited			
A.R.	No.	40000725961		Release da	ite	27 AUG 2020
Batc	h No.	5CYO220001		Quantity		13.680 Kg
Mfg.	date	02 AUG 2020		Expiry date	e	01 AUG 2025
Sr. No.	Tests		Acceptance Criteria	a / 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 Total impurities		Not more than 0.05%		Belo	w limit of quantitation
			Not more than 0.30%	One of the second second	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%		Mee	ts the requirement

Emcure Pharmaceuticals Limited

Compiled by: 😕

Operating Personnel QC

Date

: 54045050

Approved by:

Head QA /Designee

27 oct 2020

Date

Checked by: Date : 27 oct 2000

Head QC / Designee

Registered Office: Emcure House, T-184, M.I.D.C., Bhosari, Pune 411 026. INDIA
Phone Nos.: +91 20 30610000, 27120084 Fax No.: 91 - 20 - 30610111 E.Mail: corporate@emcure.co.in
CIN: U24231PN1981PLC024251

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	Certificate	Of Analysis	
Name of material	CYCLOPHOSPHAMIDE Ph.	Eur.	
Manufactured by	Emcure Pharmaceuticals Lin	nited	
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

	1 4			1100	\ r \ D \	-1 - 1 - 1	1 00 110	N.A I	1	Landay.
~1	Limit	or au	antitation	1 (LUQ) for Residu	ai solvents	DV GC-H3	ivietnoa -	I are as	pelow

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

= 0.018%

dichloride

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.

Compiled by: 🤝

Date

: 5400, 5050

Date

Checked by: La 27 oct 2020

Approved by:

Date

27 00 200

Operating Personnel QC

Head QC Designee

Head QA /(Designee)

Emcure Pharmaceuticals Limited

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