METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

002626-TDS-ENG-2020

CICLOFOSFAMIDA PH. EUR.		
DESCRIPTION DCI: CYCLOPHOSPHAMIDE	DESCRIPTION DOE: CICLOFOSFAMIDA	
CAS Nº: 6055-19-2	EC Nº: 629-456-4	AEMPS CODE: ---
MOL. WEIGHT: 279.10	MOL. FORMULA: C7H17Cl2N2O3P	ARTICLE CODE: 002626

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Soluble in water, freely soluble in alcohol
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y6
pH	4.0 - 6.0
Related substances	
Any impurity	=< 1.0 %
Chlorides	=< 330 ppm
Phosphates	=< 100 ppm
Water	6.0 - 7.0 %
Assay	98.0 - 102.0 %
Bacterial endotoxines	=< 0.20 EU/mg
Microbiological control	
TAMC	=< 100 CFU/g
TYMC	=< 10 CFU/g
Bile tol. g(-) bacteria	Absence/1g
Escherichia coli	Absence/1g
Pseudomonas aeruginosa	Absence/1g
Staphylococcus aureus	Absence/1g
Candida Albicans	Absence/1g
Clostridia	Absence/1g
Salmonella	Absence/10g
Residual solvents	
Acetone	=< 5000 ppm
Methanol	=< 3000 ppm
Methylene Chloride	=< 600 ppm
Triethylamine	=< 320 ppm

COMPLIES WITH

European Pharmacopoiea 10.0

STORAGE

Store in a cool place. Keep the container tightly closed in a dry place between 2 and 8 ºC.

REMARKS

Cyclophosphamide is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in

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accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.