

**TECHNICAL DATA SHEET**

002626-TDS-ENG-2026

<b>CICLOFOSFAMIDA MONOHIDRATO (EUR. PH.)</b>		
DESCRIPTION DCI: cyclophosphamide		DESCRIPTION DOE: CICLOFOSFAMIDA
CAS N°: 6055-19-2	EC N°: 629-456-4	AEMPS CODE: 120A
MOL. WEIGHT: 279.10	MOL. FORMULA: C <sub>7</sub> H <sub>17</sub> Cl <sub>2</sub> N <sub>2</sub> O <sub>3</sub> P	ARTICLE CODE: 002626

<b>ATTRIBUTES</b>	<b>SHOULD BE</b>
Appearance	White or almost white, crystalline powder
Solubility	Soluble in water, very soluble in methylene chloride, freely soluble in ethanol (96 %)
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y6
pH	4.0 - 6.0
Impurity G	=< 0.025 %
Related substances	
Test A	
Impurity C	=< 0.3 %
Impurity A	=< 0.15 %
Unspecified impurities	=< 0.05 %
Total impurities	=< 0.5 %
Test B	
Impurity D	=< 0.06 %
Impurity E	=< 0.06 %
Impurity F	=< 0.06 %
Any other impurity	=< 0.06 %
Chlorides	=< 330 ppm
Phosphates	=< 100 ppm
Water	6.0 - 7.0 %
Assay	98.0 - 102.0 %

**COMPLIES WITH**

European Pharmacopoeia 12.1

**STORAGE**

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

**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 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.

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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.