METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

CICLOFOSFAMIDA MONOHIDRATO (EUR. PH.)

PRODUCT CODE: 002626	CAS Nº: 6055-19-2	ANALYSIS Nº: 194/23	
MANUFACTURER BATCH:	CY-23001	CERTIFICATE ID:	38.953
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/05/2023
METAPH BATCH:	0030723	RETEST DATE:	30/04/2028

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Solubility	Soluble in water, very soluble in methylene chloride, freely soluble in ethanol (96 %)	Complies (*)
Identification B	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y6	Clear and not more intensely coloured than ref. sol. Y6
pH	4.0 - 6.0	5.1
Impurity G	=< 0.025 %	< 0.025 %
Related substances		
Test A		
Impurity C	=< 0.3 %	0.26 %
Impurity A	=< 0.15 %	< 0.03%
Unspecified impurities	=< 0.05 %	Not Detected
Total impurities	=< 0.5 %	0.26 %
Test B		
Impurity D	=< 0.06 %	< 0.06 %
Impurity E	=< 0.06 %	< 0.06 %
Impurity F	=< 0.06 %	< 0.06 %
Any other impurity	=< 0.06 %	< 0.06 %
Chlorides	=< 330 ppm	< 330 ppm
Phosphates	=< 100 ppm	< 100 ppm
Water	6.0 - 7.0 %	6.7 %
Assay	98.0 - 102.0 %	101.1 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

(*) Data adapted from the manufacturer's certificate of analysis.
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.

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.

STORAGE

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

Analysis date: 19/07/2023
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000602
AARTI INDUSTRIES LIMITED
71, Udyog Kshetra, 2nd Floor, Muulund
Goregoon Link Road
Mulund