



CICLOSPORINA A (EUR. PH.)

PRODUCT CODE: 0393	CAS Nº: 59865-13-3	ANALYSIS Nº: 215/24
MANUFACTURER BATCH: HNCN2404401E	CERTIFICATE ID: 43.259	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 04/04/2024	
METAPH BATCH: 0090824	RETEST DATE: 03/10/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. solution Y5, BY5 o R7	Complies
Specific optical rotation	-193 / -185	-190
Related substances		
Sum of impurities B and E	=< 0.5 %	0.2 %
Impurity G	=< 0.4 %	0.1 %
Any other impurity	=< 0.3 %	< 0.05 %
Total impurities	=< 1.5 %	0.3 %
Loss on drying	=< 2.0 %	0.3 %
Assay	97.0 - 102.0 %	99.3 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliances with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Ciclosporin is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

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.

STORAGE

Keep tightly closed, in a cool and dry place and protected from light.

Analysis date: 06/09/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000447