METAPHARMACEUTICAL IND SL
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CICLOSPORINA A (EUR. PH.)

PRODUCT CODE: 0393	CAS Nº: 59865-13-3	ANALYSIS Nº: 053/25	
MANUFACTURER BATCH:	HNCN2407403E	CERTIFICATE ID:	45.394
SUPPLIER BATCH:	----	MANUFACTURING DATE:	19/07/2024
METAPH BATCH:	0060325	RETEST DATE:	18/01/2028

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 %	< 0.05 %
Impurity G	=< 0.4 %	Not Detected
Any other impurity	=< 0.3 %	< 0.05 %
Total impurities	=< 1.5 %	< 0.05 %
Loss on drying	=< 2.0 %	0.1 %
Assay	97.0 - 102.0 %	99.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance 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 and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

All data controlled by Metapharmaceutical Industrial SL.

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: 23/04/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000447
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