METAPHARMACEUTICAL IND SL
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CICLOSPORINA A (EUR. PH.)

PRODUCT CODE: 0393	CAS Nº: 59865-13-3	ANALYSIS Nº: 143/23	
MANUFACTURER BATCH:	HNCN2210405E	CERTIFICATE ID:	38.429
SUPPLIER BATCH:	----	MANUFACTURING DATE:	22/10/2022
METAPH BATCH:	0270523	RETEST DATE:	21/04/2026

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	Clear and not more intensely coloured than ref. solution Y5, BY5 o R7
Specific optical rotation	-193 / -185	-187
Related substances		
Sum of impurities B and E	=< 0.5 %	0.3 %
Impurity G	=< 0.4 %	Not Detected
Any other impurity	=< 0.3 %	<0.3% (#)
Total impurities	=< 1.5 %	0.5 %
Loss on drying	=< 2.0 %	0.3 %
Assay	97.0 - 102.0 %	97.6 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

(#) Unspecified impurities detailed underneath:
TR (47.37 min) = 0.06 %
TR (56.66 min) = 0.13 %

Ciclosporin 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.

STORAGE

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

Analysis date: 29/06/2023
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000447
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