METAPHARMACEUTICAL IND SL
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TACROLIMUS MONOHIDRATADO (EUR. PH.)

PRODUCT CODE: 0316	CAS Nº: 109581-93-3	ANALYSIS Nº: 037/24	
MANUFACTURER BATCH:	P/TAC/22/12/029	CERTIFICATE ID:	41.248
SUPPLIER BATCH:	23C21-AP23103	MANUFACTURING DATE:	01/12/2022
METAPH BATCH:	0240224	EXPIRY DATE:	30/11/2025

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder (*)
Solubility	Practically insoluble in water, soluble in ethanol (96 %), practically insoluble in heptane	Complies
Identification	Complies	Complies (*)
Appearance of solution	Clear and not more intensely coloured than ref. sol. GY7	Complies
Related substances		
Impurity A	=< 0.5 %	0.43 %
Unspecified impurities	=< 0.15 %	< 0.15 %
Total impurities	=< 1.0 %	0.56 %
Water	1.5 - 4.0 %	2.6 %
Sulfated ash	=< 0.1 %	0.02 %
Assay	97.0 - 102.0 %	97.7 %

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.

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

(*) 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. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep the continers tightly closed in a fresh and dry place.

Analysis date: 14/03/2024
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000917
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