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

TACROLIMUS MONOHIDRATADO (EUR. PH.)

PRODUCT CODE: 0316	CAS Nº: 109581-93-3	ANALYSIS Nº: 042/25	
MANUFACTURER BATCH:	TACY24-16	CERTIFICATE ID:	45.261
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/12/2024
METAPH BATCH:	0160225	RETEST DATE:	30/11/2027

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 %	0.3 %
Unspecified impurities	=< 0.15 %	Not Detected
Total impurities	=< 1.0 %	0.3 %
Water	1.5 - 4.0 %	2.4 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	97.0 - 102.0 %	98.8 %

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.

Tacrolimus Monohydrate 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

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

Analysis date: 27/03/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001128
BILLS BIOTECH PVT. LTD.
Plot No.-P/01, Biotech Park Phase-1, GIDC,
Manjusar Industrail Estate
Village-Manjusar,