METAPHARMACEUTICAL

TECHNICAL DATA SHEET

0316-TDS-ENG-2026

TACROLIMUS MONOHIDRATADO (EUR. PH.)		
DESCRIPTION DCI: TACROLIMUS MONOHYDRATE	DESCRIPTION DOE: TACROLIMUS MONOHIDRATO	
CAS Nº: 109581-93-3	EC Nº: 634-559-2	AEMPS CODE: 2694MH
MOL. WEIGHT: 822	MOL. FORMULA: C44H71NO13	ARTICLE CODE: 0316

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

COMPLIES WITH

European Pharmacopoeia 12.3

STORAGE

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

REMARKS

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

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.

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