

TACROLIMUSUM MONOHYDRICUM 10 g

Lot No.: 23C21-AP23103

Autorisation :	1890IR06139	Date Of Analysis :	21/03/2023
Analytical Reference :	Ph.Eur. 11.0 (01/2018:2244)	Production Number :	130623-0170223
CNK :	4701-850	Expiry Date :	11/2025

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
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	SPECIFICATION	RESULT
Identification	Complies	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than ref.sol.GY7	Complies
Related substances		
Impurity A	$\leq 0.5 \%$	0.43 %
Unspecified impurities	$\leq 0.15 \%$	< 0.15 %
Total impurities	$\leq 1.0 \%$	0.56 %
Water	1.5 – 4.0 %	2.6 %
Sulfated ash	$\leq 0.1 \%$	0.02 %
ASSAY	SPECIFICATION	RESULT
Assay	97.0 – 102.0 %	97.7 %

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST:

Joran Smout
(Signature)

Digitally signed by Joran
Smout (Signature)
Date: 2023.08.04
13:55:09 +02'00'

METAPHARMACEUTICAL

N DE LOTE:

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 26/02/2024