EUTICALS
The Pharmaceutical & Fine Chemical Company

PRIME EUROPEAN THERAPEUTICALS SpA - Sole Shareholder
Registered Office: Viale Bianca Maria, 25 - 20122 Milano - Administrative Office: Viale Milano, 86/88 – 26900 Lodi
Tax Code - VAT Number – Trade Register of Milano n. 07254610152 - R.E.A. MI-1851470 - Share capital 34.370.805,46 fully paid

CERTIFICATE OF ANALYSIS

Product : **TACROLIMUS**

Batch no.: **IE1300799A** Code: **30127**

Manufacturing date: **October 2013** Analysis date: **November 2013** Re-test date: **October 2017**

TEST	SPECIFICATIONS	ANALYSIS VALUE
Characters	white to off-white crystalline powder.	complies
Identification IR	must comply to the standard	complies
Identification	it gives positive reaction with 1,3-dinitro benzene	complies
Identification HPLC	must comply to the standard	complies
Water (K.F.)	between 1.9 % and 2.5 %	2.3 %
Sulphated ash	not more than 0.1 %	0.1 %
Heavy metals	not more than 10 ppm	less than 10 ppm
Specific optical rotation	between - 115° and - 112°	- 115°
Assay, on dried basis (HPLC)	between 98.0 % and 102.0 %	100.2 %
Related substances (HPLC)		
- Tacrolimus metacrilate	not more than 0.2 %	not detectable
- Tacrolimus diene	not more than 0.2 %	not detectable
- Ascomycin	not more than 0.5 %	0.1 %
- Propyl-derivate	not more than 0.1 %	not detectable
- Tautomer II	not more than 1.0 %	0.2%
- Tautomer I	not more than 0.5 %	not detectable
- Largest unspecified	not more than 0.2 %	not detectable
- Total (*)	not more than 0.8 %	0.2 %
Residual solvent		
Acetone	not more than 5000 ppm	26 ppm
Ethyl acetate	not more than 5000 ppm	not detectable
n-Heptane	not more than 5000 ppm	not detectable
TAMC	not more than 100 ufc/g	< 10 cfu/g
TYMC	not more than 10 ufc/g	< 10 cfu/g

(*) Total impurities does not include Tautomer II and Tautomer I

Milan – February 6, 2014

Q.C. Manager

DR.SSA MICHELA RAMPI

This is to certify that the batch was manufactured according to c-GMP.

Qualified Person

DR. STEFANO BRUSCO

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