

CERTIFICATE OF ANALYSIS

Product : **TACROLIMUS**

MANUFACTURING SITE EUTICALS SpA - Via Valtorno 41/43 - 20089 Rozzano (MI)

Batch no.: **IE1300799A**

Code: **30127**

Manufacturing date: **October 2013**

Analysis date: **November 2013**

Re-test date: **October 2017**

<u>TEST</u>	<u>SPECIFICATIONS</u>	<u>ANALYSIS VALUE</u>
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 %
<i>Related substances (HPLC)</i>		
- 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 %
<i>Residual solvent</i>		
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 - March 24, 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

Production Units - Lodi Area

Viale Milano, 86/88
26900 Lodi (LO) ITALY
Tel +39 0371 4902 1
Fax +39 0371 610019

Via delle Rimembranze, 1
26852 Casaleggio Lodigiano (LO) ITALY
Tel +39 0371 7397 1
Fax +39 0371 71793

Production Units - Milano Area

Via Valtorno, 41/43
20089 Rozzano (MI) ITALY
Tel +39 02 82272 1
Fax +39 02 8246183

Via Monte Rosa, 114/116
20089 Rozzano (MI) ITALY
Tel +39 02 822835 1
Fax +39 02 8250573

Production Units - Varese Area

Via Valverde, 20/22
21100 Varese (VA) ITALY
Tel +39 0332 2299 1
Fax +39 0332 212575

Viale Europa, 5
21040 Origgio (VA) ITALY
Tel +39 02 969531
Fax +39 02 96730456