

Lote: 0120316



Flamma s.p.a.

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CERTIFICATE OF ANALYSIS

MODAFINIL MICRO

2-(benzhydrysulfinyl)acetamide

BATCH	126003	CODE	FC00000104
QUANTITY	KG - 21	SPEC. CODE	FC00000104
MANUFACTURING DATE	11/02/2013	REV.	0
RETEST DATE	16/01/2018	REFERENCE	USP/EP
ANALYSIS DATE	12/02/2013	ANALYTICAL REPORT NR.	2013000392

TESTS	LIMITS			RESULTS
	M.U.	MIN	MAX	
ASPECT			CRYSTALLINE POWDER	COMPLIES
COLOUR			WHITE	COMPLIES
IDENTIFICATION (IR)			MUST COMPLY	COMPLIES
IDENTIFICATION (HPLC)			MUST COMPLY	COMPLIES
WATER CONTENT	%		0.2	0.0
ASSAY (HPLC)	% d.b.	98.0	101.5	99.1
EACH UNKNOWN IMPURITY (HPLC)	%		0.05	0.00
MODAFINIL ACID (IMP. A) (HPLC)	%		0.2	0.0
MODAFINIL SULFONE (IMP. B) (HPLC)	%		0.5	0.0
MODAFINIL ESTER (IMP. C) (HPLC)	%		0.5	0.0
TOTAL IMPURITIES (HPLC)	%		1.0	0.1
RESIDUAL METHYL ALCOHOL	ppm		3000	15
RESIDUAL THF	ppm		720	0
HEAVY METALS	ppm		20	< 20
RESIDUE ON IGNITION	%		0.1	0.0
PARTICLE SIZE 90%	micron		100	44
PARTICLE SIZE 50%	micron		40	13
PARTICLE SIZE 10%	micron		10	2

APPROVED

QUALITY CONTROL

Dr. Stefano Gobbato

NOTE: This certificate of analysis has been generated electronically and it is valid without a signature
Unique identification is assigned by batch number + compound code