

MANUFACTURING SITE Via Bedeschi, 22 - 24040 CHIGNOLO D'ISOLA (BG) - Italy



Flamma s.p.a.

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CERTIFICATE OF ANALYSIS

MODAFINIL MICRO

2-(benzhydrylsulfinyl)acetamide

BATCH
QUANTITY
MANUFACTURING DATE
RETEST DATE

126002
KG - 69,45
11/02/2013
16/01/2018

CODE
REFERENCE
ANALYTICAL REPORT NR.
ANALYSIS DATE

FC00000104
USP/EP
2013000391
12/02/2013

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	98.7
EACH UNKNOWN IMPURITY (HPLC)	%		0.05	0.04
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	28
RESIDUAL THF	ppm		720	8
HEAVY METALS	ppm		20	< 20
RESIDUE ON IGNITION	%		0.1	0.0
PARTICLE SIZE 90%	micron		100	49
PARTICLE SIZE 50%	micron		40	5
PARTICLE SIZE 10%	micron		10	1

APPROVED

QUALITY CONTROL

Dr. Stefano Gobbato

NOTE: This certificate of analysis has been generated electronically and it is valid without a signature