



Flamma s.p.a.

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CERTIFICATE OF ANALYSIS

MODAFINIL

2-(benzhydrylsulfinyl)acetamide

BATCH	130001	CODE	3203070003
QUANTITY	KG - 85	REFERENCE	USP/EP
MANUFACTURING DATE	05/02/2013	ANALYTICAL REPORT NR.	2013000340
RETEST DATE	10/01/2018	ANALYSIS DATE	01/03/2013

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	99.5
EACH UNKNOWN IMPURITY (HPLC)	%		0.05	0.02
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	0.0
RESIDUAL METHYL ALCOHOL	ppm		3000	150
RESIDUAL THF	ppm		720	97
HEAVY METALS	ppm		20	< 20
RESIDUE ON IGNITION	%		0.1	0.0

APPROVED

QUALITY CONTROL

Dr. Stefano Gobbato

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