

CERTIFICATE OF ANALYSIS

MODAFINIL

2-(benzhydrysulfinyl)acetamide

BATCH	120001	CODE	3203070003
QUANTITY	KG - 67	REFERENCE	USP/EP
MANUFACTURING DATE	28/02/2012	ANALYTICAL REPORT NR.	2012000521
RETEST DATE	01/02/2017	ANALYSIS DATE	23/03/2012

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	0.03
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	261
RESIDUAL THF	ppm		720	37
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