

CERTIFICATE OF ANALYSIS**MINOXIDIL USP/EP MILLED****6-(1-piperidinyl)-2,4-pyrimidine
diamine 3-oxide**

BATCH	166102	CODE	FC00000185
QUANTITY	KG - 823,5	SPEC. CODE	FC00000185
MANUFACTURING DATE	19/10/2016	REV.	0
RETEST DATE	23/09/2021	REFERENCE	USP/EP
ANALYSIS DATE	14/04/2017	ANALYTICAL REPORT NR.	2017001065

TESTS	LIMITS			RESULTS
	M.U.	MIN	MAX	
ASPECT			CRYSTALLINE POWDER	CRYSTALLINE POWDER
COLOUR			WHITE TO ALMOST WHITE	WHITE
IDENTIFICATION (IR, HPLC)			MUST COMPLY	COMPLIES
IDENTIFICATION (UV)			MUST COMPLY	COMPLIES
SOLUBILITY (2% w/v prop.gly/et.al 70/10)			COMPLETE	COMPLIES
SOLUBILITY (2% w/v methyl alcohol 50%)			COMPLETE	COMPLIES
CLARITY, COLOUR SOLUTION			CLEAR <Y6	COMPLIES
LOSS ON DRYING (50°C u.v.)	%		0.3	0.1
PURITY (HPLC)	%	99.7		100.0
TOTAL IMPURITIES (HPLC)	%		0.3	0.0
N-OXIDE (HPLC)	%		0.10	< 0.05
CHLORODAP (HPLC)	%		0.10	< 0.05
DPP (HPLC)	%		0.10	< 0.05
EACH UNKNOWN IMPURITY (HPLC)	%		0.10	< 0.05
ASSAY (HPLC)	% d.b.	98.5	101.0	99.2
ASSAY (HClO ₄ , potentiometric)	% d.b.	99.0	101.0	100.2
RESIDUE ON IGNITION	%		0.1	0.0
HEAVY METALS	ppm		20	< 20
TUNGSTEN	ppm		1.0	< 0.2
RESIDUAL ACETONE (GC)	ppm		500	< 5
METHYL ALCOHOL (GC)	ppm		2	< 2
RESIDUAL ACETIC ACID	ppm		1000	571
PARTICLE SIZE (D10)	micron		5	3
PARTICLE SIZE (D50)	micron		15	7

NOTES: Colour White 07/04/17 EG

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

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TESTS	LIMITS			RESULTS
	M.U.	MIN	MAX	
PARTICLE SIZE (D90)	micron		30	15

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