

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

BATCH	170076	CODE	3201007011
QUANTITY	KG - 393,3	SPEC. CODE	3201007011
MANUFACTURING DATE	18/06/2017	REV.	22
RETEST DATE	23/05/2022	REFERENCE	USP/EP
ANALYSIS DATE	12/07/2017	ANALYTICAL REPORT NR.	2017001912

TESTS	LIMITS		RESULTS
	M.U.	MIN MAX	
ASPECT		CRYSTALLINE POWDER	COMPLIES
COLOUR		WHITE TO ALMOST WHITE	COMPLIES
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	99.6
ASSAY (HClO4, potentiometric)	% d.b.	99.0 101.0	100.3
RESIDUE ON IGNITION	%	0.1	0.0
HEAVY METALS	ppm	20	< 20
TUNGSTEN	ppm	1.0	< 0.2
RESIDUAL ACETONE (GC)	ppm	500	16
METHYL ALCOHOL (GC)	ppm	2	< 2
RESIDUAL ACETIC ACID	ppm	1000	358

NOTES: Colour: White FD 23/06/17

APPROVED

QUALITY CONTROL

Dr. Stefano Gobbato