Macsen Laboratories
Manufacturer of Fine Chemicals & Pharmaceuticals

SPECIFICATION SHEET

Name of product : Minoxidil Ph. Eur

CAS No. : 38304-91-5

Molecular weight : 209.3 g/mol

SR.NO	CRITERIA	SPECIFICATION
1.	**APPEARANCE**	White or almost white, crystalline powder.
2.	**SOLUBILITY**	Slightly soluble in water, soluble in methanol and in propylene glycol.
3.	**IDENTIFICATION**	
	Test A: By UV	1) The UV absorption spectrum should exhibit absorption maxima at approximately 230 nm and 281 nm for test solution A 2) Th e UV absorption spectrum should exhibit absorption maxima at approximately 230 nm, 262 nm and 288 nm for test solution B
	Test B: By IR	The infrared spectrum of test sample should match with working standard / reference standard
	Test C: By TLC	The principal spot in the chromatogram obtained with the test solution corresponds in position, color and size to the principal spot obtained with the reference solution.
	Test D: Chemical Test (Copper Sulphate Test)	A green colour develops on addition of copper sulphate solution. On subsequent addition of 0.1mL of dilute hydrochloric acid, the solution becomes greenish-yellow.
5.	**SULPHATED ASH**	NMT 0.1%
6.	**LOSS ON DRYING**	NMT 0.5%
7	**ASSAY BY HPLC (On dried basis)**	NLT 99.0% to NMT 101.0%

8	**RELATED SUBSTANCE BY HPLC**	

Name	Acceptance Criteria, NMT (%)
Impurity E: 6-(piperidin-1-yl) pyrimidine-2,4-diamine	NMT 0.2%
Impurity B: 6-chloropyrimidine2,4-diamine	NMT 0.15%
Impurity A: 6-chloropyrimidine-2,4-diamine 3-oxide,	NMT 0.10%
Unspecified Impurities	NMT 0.10%
Total Impurities	NMT 0.3%