

KUMAR ORGANIC PRODUCTS LIMITED



CERTIFICATE OF ANALYSIS

0Name of the Product	MINOXIDIL EP	Batch No.	K007.2/25/09/498
Analytical report no.	FP/K007/SB/25/523	Mfg. Date	SEPTEMBER -2025
Date of analysis	03.10.2025	Exp. Date	AUGUST -2030
Qty being dispatched	200.0 Kg	Mfg.Licence No.	KTK/25/624/2013
CEP No.	CEP 2013-310-Rev 02		

	SI No.	TEST	SPECIFICATION	RESULT
	1	Appearance	White or almost white, crystalline powder	White crystalline powder
	2	Solubility	Slightly soluble in water, soluble in methanol, and in propylene glycol	Complies
	3	Identification	The IR absorption spectrum of the sample should be concordant with	7,
		By IR Absorption spectrophotometry	the IR absorption spectrum on Minoxidil working standard.	Complies
4 In		Impurities		
	A.	Sulphated ash	Maximum 0.1%	0.02%
	B.	Related substances by HPLC	1 7	
		B. Related substances by HPLC a. Impurity E b. Impurity B c. Single largest unknown impurity d. Total Impurities	Maximum 0.2% Maximum 0.15% Maximum 0.10% Maximum 0.3%	Not detected Not detected 0.01% 0.01%
	C. Additional Test		7	4 1000 mm
		Piperidine by GC-HS	Not more than 1000 ppm	< 1000 ppm
	5	-Loss-on-drying	Maximum-0.5%	0.11%
	6.	Assay by Potentiometry (on dried basis)	99.0% to 101.0% C ₉ H ₁₅ N ₅ O Calculated on dried substance	100.2%
	7	Residual solvents by GC-HS 1. Methanol	Not more than 3000 ppm	< 3000 ppm

Remarks: The above sample complies with the EP 11.0 standard.

Compiled by

QC Executive QC Manager QC Executive

Approved by QA Manager

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METAPHARMACEUTICAL

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