



KUMAR ORGANIC PRODUCTS LIMITED

CERTIFICATE OF ANALYSIS

Name of the Product	MINOXIDIL EP	Batch No.	K007.1/21/11/317
Analytical report no.	FP/K007/SB/21/385	Mfg. Date	NOVEMBER -2021
Date of analysis	29.11.2021	Exp. Date	OCTOBER-2025
Qty being dispatched	150.0Kg	Mfg.Licence No.	KTK/25/624/2013
CEP NO.	R1-CEP 2013-310-REV 00		

Sl No.	TEST	SPECIFICATION	RESULT
1	Appearance	White or almost white, crystalline powder	Almost white, crystalline powder
2	Solubility	Slightly soluble in water, soluble in methanol and in propylene glycol.	Complies
3	Identification By IR Absorption spectrophotometry	The IR absorption spectrum of the sample should be concordant with the IR absorption spectrum of Minoxidil working standard	Complies
4	Related substances		
	A. Related substances by GC-HS a. Piperidine	Maximum 1000 ppm	< 1000 ppm
	B. Related substances by HPLC a. Impurity E b. Impurity B c. Single largest unknown impurity d. Total Impurities	Maximum 0.20% Maximum 0.15% Maximum 0.10% Maximum 0.3%	Below Detection Limit Below Detection Limit 0.03% 0.09%
5	Loss on drying	Maximum 0.5%	0.12%
6	Sulfated ash	Maximum 0.1%	0.03%
7	Assay by potentiometry (on dried basis)	99.0% to 101.0%	99.7%
8	Residual solvents by GC-HS 1. Methanol	Not more than 3000 ppm	< 3000 ppm

Remarks: The above sample complies with the EP 10 standards.

Compiled by

QC Executive

Verified by

QC Manager

Approved by

QA Manager

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METAPHARMACEUTICAL

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