



KUMAR ORGANIC PRODUCTS LIMITED

F&amp;A PHARMA

## CERTIFICATE OF ANALYSIS

Name of the Product	MINOXIDIL EP	Batch No.	K007.2/23/02/069
Analytical report no.	FP/K007/SB/23/076	Mfg. Date	FEBRUARY-2023
Date of analysis	24.02.2023	Exp. Date	JANUARY -2028
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 on Minoxidil reference standard.	Complies
4	Impurities		
A.	Sulphated ash	Maximum 0.1%	0.02%
B.	Related substances by HPLC		
	B. Related substances by HPLC		
	a. Impurity E	Maximum 0.2%	Not Detected
	b. Impurity B	Maximum 0.15%	Not Detected
	c. Single largest unknown impurity	Maximum 0.10%	0.02%
	d. Total Impurities	Maximum 0.3%	0.05%
C.	Additional Test		
	Piperidine by GC-HS	Not more than 1000 ppm	< 1000 ppm
5	Loss on drying	Maximum 0.5%	0.10%
6	Assay by Potentiometry (on dried basis)	99.0% to 101.0% $C_9H_{15}N_3O$ Calculated on dried substance	99.7%
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

Verified by

Approved by

QC Executive

QC Manager

QA Manager

Kumar Organic Products Limited, Plot No.60&65, Road No. 3, Jigani Industrial Area, Jigani, Anekal Taluk, Bangalore, India-560105



METAPHARMACEUTICAL

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05/09/2023