



KUMAR ORGANIC PRODUCTS LIMITED



CERTIFICATE OF ANALYSIS

Name of the Product	MINOXIDIL EP	Batch No.	K007.2/23/08/370
Analytical report no.	FP/K007/SB/23/421	Mfg. Date	AUGUST -2023
Date of analysis	21.08.2023	Exp. Date	JULY -2028
Qty being dispatched	150.0Kg	Mfg.Licence No.	KTK/25/624/2013

Sl 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 By IR Absorption spectrophotometry	The IR absorption spectrum of the sample should be concordant with the IR absorption spectrum on Minoxidil working 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%	Below disregard
	b. Impurity B	Maximum 0.15%	Not detected
	c. Single largest unknown impurity	Maximum 0.10%	0.01%
	d. Total Impurities	Maximum 0.3%	0.03%
C.	Additional Test		
	Piperidine by GC-MS	Not more than 1000 ppm	< 1000 ppm
5	Loss on drying	Maximum 0.5%	0.12%
6	Assay by Potentiometry (on dried basis)	99.0% to 101.0% $C_9H_{15}N_5O$ Calculated on dried substance	100.4%
7	Residual solvents by GC-MS 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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18/12/2023

