

KUMAR ORGANIC PRODUCTS LIMITED

F&A PHARMA

CERTIFICATE OF ANALYSIS

.Name of the Product	MINOXIDIL EP	Batch No.	K007.2/23/01/033
Analytical report no.	FP/K007/SB/23/040	Mfg. Date	JANUARY -2023
Date of analysis	01.02.2023	Exp. Date	DECEMBER -2027
Qty being dispatched	50.0Kg	Mfg.Licence No.	KTK/25/624/2013
CEP No.	R1-CEP 2013-310-Rev 00	3	AXXIXIB3/024/2013

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	A. Related substances by GC-HS a. Piperidine B. Related substances by HPLC a. Impurity B b. Impurity E c. Single largest unknown impurity	Maximum 1000 ppm Maximum 0.15% Maximum 0.2% Maximum 0.10%	< 1000 ppm Not Detected Not Detected 0.01%
5	d.Total Impurities Loss on drying	Maximum 0.3% Maximum 0.5%	0.04%
6	Sulfated ash	Maximum 0.1%	0.02%
7	Assay by potentiometry (on dried basis)	99.0% to 101.0%	100.3%
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

Verified by

Approved by

QC Executive

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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Page No. 1 of 1