F&A PHARMA



KUMAR ORGANIC PRODUCTS LIMITED

CERTIFICATE OF ANALYSIS

Name of the Product	MINOXIDIL EP	Batch No.	K007.2/24/09/375
Analytical report no.	FP/K007/SB/24/413	Mfg. Date	SEPTEMBER -2024
Date of analysis	25.09.2024	Exp. Date	AUGUST -2029
Qty being dispatched	150.0Kg	Mfg.Licence No.	KTK/25/624/2013
CEP No.	CEP 2013-310-Rev 02		1 1

SI No.	TEST	SPECIFICATION	RESULT
l -	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 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 0.02% 0.06%
C.	Additional Test		
	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	100.1%
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 19/10/2021

Verified by

QC Manager 19/10/2014

Approved by

QA Manager

Kumar Organic Products Limited, Plot No.60 & 65, 62 & 64, Road No. 3 & 5, Jigani Industrial Area, Jigani, Anekal Taluk, Bangalore, India-560105

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