F&A PHARMA

KUMAR ORGANIC PRODUCTS LIMITED

CERTIFICATE OF ANALYSIS

COPY QA APPROVED Date 13.09.24 Signature

Name of the Product	**MINOXIDIL EP**	**Batch No.**	**K007.2/24/08/320**
Analytical report no.	**FP/K007/SB/24/368**	**Mfg. Date**	**AUGUST -2024**
Date of analysis	**03.09.2024**	**Exp. Date**	**JULY -2029**
Qty being dispatched	**150.0Kg**	**Mfg.Licence No.**	**KTK/25/624/2013**
CEP No.	**CEP 2013-310-Rev 02**		

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 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 0.01% 0.02%
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% $C_9H_{15}N_5O$ Calculated on dried substance	99.9%
7	Residual solvents by GC-HS 1. Methanol	Not more than 3000 ppm	< 3000 ppm
8	particle size *	D90 - Information	254 Micron

Remarks: The above sample complies with the EP 11.0 standard.

*As per customer requirement

Compiled by: QC Executive 04/09/2024

Verified by: QC Manager 04/09/2024

Approved by: QA Manager 04/09/2024.

METAPHARMACEUTICAL

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18/09/2024.