



## KUMAR ORGANIC PRODUCTS LIMITED

## CERTIFICATE OF ANALYSIS



Name of the Product	MINOXIDIL USP 43 (MICRONISED)	Batch No.	K007.1/25/10/536
AR. No.	FP/K007/SB/25/606	Mfg. Month	OCTOBER -2025
Date of analysis	17.11.2025	Exp. Month	SEPTEMBER -2030
Qty being dispatched	125.0 Kg	Mfg. Licence No.	KTK/25/624/2013
CAS NO.	38304-91-5		

Sl. No.	TEST	SPECIFICATION	RESULTS
1	Description	a. White to off-white crystalline powder.	White crystalline powder
		b. Melts between 248 °C to 268 °C, with decomposition.	252.5 – 253.4°C
2	Solubility	Soluble in alcohol and in propylene glycol, sparingly soluble in methanol, slightly soluble in water. Practically insoluble in chloroform, acetone, ethyl acetate and in hexane.	Complies
3	a. By IR Absorption spectrum	The infrared absorption spectrum of the sample should be concordant with the IR absorption spectrum of Minoxidil working standard.	Complies
	b. By HPLC	The retention time of the Minoxidil peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	Complies
4	Assay by HPLC ( on dried basis )	NLT 97.0% and NMT 103.0%	100.0%
5	Impurities		
a.	Residue on ignition	NMT 0.5%	0.02%
b.	Organic Impurities by HPLC		
	a. 4-Chloropyrimidine-2,6-diamine-1-oxide (Pyrimidine oxide analog)	Not more than 0.20%	0.015%
	b. 6-Chloropyrimidine-2,4-diamine (Pyrimidine analog)	Not more than 0.20%	Not Detected
	c. 6-(Piperidin-1-yl)pyrimidine-2,4-diamine (deoxyminoxidil)	Not more than 0.20%	0.002%
	d. Any individual unspecified impurities	Not more than 0.10%	0.003%
	e. Total impurities	Not more than 1.0%	0.020%
c.	Additional Test		
	Piperidine by GC-HS	Not more than 1000 ppm	< 1000 ppm
6	Loss on drying	Not more than 0.5%	0.11%
7	Residual solvents by GC-HS Methanol	Not more than 3000 ppm	< 3000 ppm
8	Particle size *	D50 - Information D90 - Information	39 micron 93 micron
9	Heavy Metals*	Not more than 20 ppm	< 20 ppm

Remarks: The above sample complies with the USP 43 standard.

\*As per customer requirement

Compiled by

QC Executive

Verified by

QC Manager

Approved by

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