



KUMAR ORGANIC PRODUCTS LIMITED

CERTIFICATE OF ANALYSIS

Name of the Product	MINOXIDIL USP 43	Batch No.	K007.1/21/10/262
AR. No.	FP/K007/SB/21/313	Mfg. Month	OCTOBER -2021
Date of analysis	18.10.2021	Exp. Month	SEPTEMBER-2025
Qty being dispatched	200.0Kg	Mfg. Licence No.	KTK/25/624/2013
CAS NO.	38304-91-5		
Sl. No.	TEST	SPECIFICATION	RESULTS
1	Description	White to off-white crystalline powder. Melts between 248 °C to 268 °C, with decomposition.	White crystalline powder 252.2 – 253.5°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	Identification a. By IR Absorption spectrum b. By HPLC	The infrared absorption spectrum of the sample should be concordant with the IR absorption spectrum of Minoxidil working standard. The retention time of the Minoxidil peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	Complies Complies
4	Assay by HPLC (on dried basis)	NLT 97.0% and NMT 103.0%	99.7%
5	Impurities		
a.	Residue on ignition	NMT 0.5%	0.02%
b.	Organic Impurities by HPLC		
	a. 4-Chloropyrimidine-2,6-diamine-1-oxide	Not more than 0.2%	Below Detection Limit
	b. 6-Chloropyrimidine-2,4-diamine	Not more than 0.2%	Below Detection Limit
	c. 6-(Piperidin-1-yl)pyrimidine-2,4-diamine (deoxyminoxidil)	Not more than 0.2%	0.11%
	d. Any individual unspecified impurities	Not more than 0.1%	0.08%
	e. Total impurities	Not more than 1.0%	0.18%
6	Loss on drying	Not more than 0.5%	0.14%
7	Residual solvents by GC-HS Methanol Piperidine	Not more than 500 ppm Not more than 1000 ppm	< 500 ppm < 1000 ppm
8	Particle size	D90 < 150 micron	18 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

Verified by

Approved by

QC Executive

QC Manager

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