



KUMAR ORGANIC PRODUCTS LIMITED

CERTIFICATE OF ANALYSIS

Name of the Product	MINOXIDIL USP	Batch No.	K007.1/19/07/155
AR. No.	FP/K007/SB/19/173	Mfg. Month	JULY -2019
Date of analysis	10.08.2019	Exp. Month	JUNE - 2023
Qty being dispatched	50.0Kg	Mfg.Licence No.	KTK/25/624/2013
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 – 254.8°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 By IR Absorption spectrum	The infrared absorption spectrum of the sample should be concordant with the IR absorption spectrum of Minoxidil working standard	Complies
4	Assay by HPLC (on dried basis)	NLT 97.0% and NMT 103.0%	99.2%
5	Impurities		
a.	Residue on ignition	NMT 0.5%	0.02%
b.	Organic Impurities by HPLC Total Impurities	NMT 1.5%	0.9%
6	Loss on drying	NMT 0.5%	0.07%
7	Residual solvents by GC-HS Methanol Piperidine	Not more than 3000 ppm Not more than 1000 ppm	< 3000 ppm < 1000 ppm

Remarks: The above sample complies with the USP 41 standard.

Compiled by

8/10/08/11

QC Executive

Verified by

10/08/2019

QC Manager

Approved by

10/08/2019

QA Manager

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