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CERTIFICATE OF ANALYSIS

Name of the Product	MINOXIDIL EP	Batch No.	K007.1/20/06/135
Analytical report no.	FP/K007/SB/20/155	Mfg. Date	JUNE -2020
Date of analysis	29.06.2020	Exp. Date	MAY-2024
Qty being dispatched	150.0Kg	Mfg.Licence No.	KTK/25/624/2013
CEP No.	RO-CEP 2013-310 REV 00		

SI No.	TEST	SPECIFICATION	RESULT
1	Appearance	White or almost white, crystalline powder	Almost white, crystalline powder
2	Solubility	Slightly soluble in water, soluble in methanol and in propylene glycol.	Complies
3	Identification	The IR absorption spectrum of the	
	By IR Absorption spectrophotometry	sample should be concordant with the IR absorption spectrum of Minoxidil working standard	Complies
4	Related substances		
	A. Related substances by GC-HS a. Piperidine	Maximum 1000 ppm	< 1000 ppm
	B. Related substances by HPLC a. Impurity E b. Impurity B c. Single largest unknown impurity d.Total Impurities	Maximum 0.15% Maximum 0.15% Maximum 0.10% Maximum 0.3%	Below Detection Limit Below Detection Limit 0.01% 0.01%
5	Loss on drying	Maximum 0.5%	0.09%
6	Sulfated ash	Maximum 0.1%	0.03%
7	Assay by potentiometry (on dried basis)	99.0% to 101.0%	99.4%
8	Residual solvents by GC-HS 1. Methanol	Not more than 3000 ppm	< 3000 ppm

Remarks: The above sample complies with the EP 10 standards.

Compiled by

QC Executive

Verified by

QC Manager

QA Manager

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