

CERTIFICATE OF ANALYSIS

Product Name	MINOXIDIL USP		
Batch Number	25RDMNX001	A. R. No.	25RD0009
Mfg. Date	DEC-2025	Batch Quantity	1.00 KG
Exp. Date / Retest Date	NOV-2030	Date of Release	06-12-2025
Specification No.	SPC/FP/022	CAS Number	38304-91-5

S. No.	TEST	SPECIFICATION	RESULT
01.	Description	White to off-white crystalline, powder.	Off white crystalline powder.
02.	Solubility	Soluble in methanol and in propylene glycol, slightly soluble in water, very slightly soluble in ether, practically insoluble in chloroform, ethyl acetate, acetone and n-hexane.	Complies
03.	Identification a) By IR	Compare the spectrum of the minoxidil sample to be examined with the spectrum obtained from minoxidil reference standard.	Complies
	b) By Assay	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	Complies
04.	Loss on drying (%w/w)	Not more than 0.5%	0.12%
05.	Melting Range (°C)	Between 248°C to 268°C	254.2°C to 255.3°C
06.	Residue On Ignition (%w/w)	Not more than 0.5 %	0.02%
07.	Organic impurity (%w/w by HPLC)		
	Pyrimidine oxide analog	Not more than 0.2	0.02%
	Pyrimidine analog	Not more than 0.2	Not detected
	Deoxyminoxidil	Not more than 0.2	Not detected
	Individual unspecified impurity	Not more than 0.1	0.04%
	Total impurities	Not more than 1.0	0.16%
08.	Assay by HPLC (%w/w as C ₉ H ₁₅ N ₅ O on dried basis)	Not less than 97.0% and not more than 103.0%	99.82%
09.	Residual solvent by GC-HS (ppm)		
	Methanol	Not more than 3000 ppm	239
	Piperidine	Not more than 5000 ppm	Not detected

Storage Condition: Store in a well-closed container and protect from direct light.

REMARK: The product **Complies** / ~~Does Not Comply~~ as per the above specification.