



KUMAR ORGANIC PRODUCTS LIMITED

F&A PHARMA

CERTIFICATE OF ANALYSIS

| | | | |
|-----------------------|------------------------|-----------------|------------------|
| Name of the Product | MINOXIDIL EP | Batch No. | K007.2/23/08/373 |
| Analytical report no. | FP/K007/SB/23/431 | Mfg. Date | AUGUST -2023 |
| Date of analysis | 30.08.2023 | Exp. Date | JULY -2028 |
| Qty being dispatched | 125.0Kg | Mfg.Licence No. | KTK/25/624/2013 |
| CEP NO. | R1-CEP 2013-310-Rev 00 | | |

| Sl No. | TEST | SPECIFICATION | RESULT |
|--------|--|--|--------------------------|
| 1 | Appearance | White or almost white, crystalline powder | White crystalline powder |
| 2 | Solubility | Slightly soluble in water, soluble in methanol, and in propylene glycol | Complies |
| 3 | Identification By IR Absorption spectrophotometry | The IR absorption spectrum of the sample should be concordant with the IR absorption spectrum on Minoxidil working standard. | Complies |
| 4 | Impurities | | |
| A. | Sulphated ash | Maximum 0.1% | 0.02% |
| B. | Related substances by HPLC | | |
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| | a. Impurity E | Maximum 0.2% | Below disregard |
| | b. Impurity B | Maximum 0.15% | Not detected |
| | c. Single largest unknown impurity | Maximum 0.10% | 0.02% |
| | d. Total Impurities | Maximum 0.3% | 0.06% |
| C. | Additional Test | | |
| | Piperidine by GC-HS | Not more than 1000 ppm | < 1000 ppm |
| 5 | Loss on drying | Maximum 0.5% | 0.11% |
| 6 | Assay by Potentiometry (on dried basis) | 99.0% to 101.0% $C_9H_{15}N_5O$ Calculated on dried substance | 99.1% |
| 7 | Residual solvents by GC-HS L. Methanol | Not more than 3000 ppm | < 3000 ppm |

Remarks: The above sample complies with the EP 11.0 standard.

Compiled by

Verified by

Approved by

QC Executive

QC Manager

QA Manager

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METAPHARMACEUTICAL

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22/10/2024