



Letco Medical, LLC.

| DATE CREATED                   | REVISION | PAGE   |
|--------------------------------|----------|--------|
| May 23, 2024                   | 00       | 1 of 2 |
| <b>CERTIFICATE OF ANALYSIS</b> |          |        |

|                    |            |            |            |            |            |  |  |
|--------------------|------------|------------|------------|------------|------------|--|--|
| <b>Letco Item:</b> | 686365     | 686366     | 691084     | 696983     | 697129     |  |  |
| <b>Letco Lot:</b>  | 2404160021 | 2404160022 | 2404160023 | 2404160024 | 2404160025 |  |  |

| DESCRIPTION   | SOURCE LOT       | DATE OF MANUFACTURE | EXPIRATION DATE |
|---------------|------------------|---------------------|-----------------|
| Minoxidil USP | K007.1/24/04/137 | April 2024          | March 2029      |

| TEST   | SPECIFICATION  | RESULT                   |
|--|--|--------------------------|
| Description  | White to off-white crystalline powder.   | White crystalline powder |
|  | Melts between 248°C to 268°C, with decomposition.  | 252.4 – 253.5°C          |
| 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                 |
| <b>Identification</b>                                      |  |                          |
| By IR Absorption spectrum                                  | The infrared absorption spectrum of the sample should be concordant with the IR absorption spectrum of Minoxidil working standard.   | Complies                 |
| By HPLC  | The retention time of the Minoxidil peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.  | Complies                 |
| Assay by HPLC (on dried basis)                             | NLT 97.0% and NMT 103.0%   | 99.7%                    |
| <b>Impurities</b>  |  |                          |
| Residue on ignition  | NMT 0.5%   | 0.02%                    |
| <b>Organic Impurities by HPLC</b>                          |  |                          |
| 4-Chloropyrimidine-2,6-diamine-1-oxide                     | Not more than 0.2%   | 0.02%                    |
| 6-Chloropyrimidine-2,4-diamine                             | Not more than 0.2%   | Not Detected             |
| 6-(Piperidin-1-yl) pyrimidine-2,4-diamine (deoxyminoxidil) | Not more than 0.2%   | 0.004%                   |
| Any individual unspecified impurities                      | Not more than 0.1%   | 0.004%                   |
| Total Impurities   | Not more than 1.0%   | 0.02%                    |
| Piperidine by GC-HS  | Not more than 1000 ppm   | < 1000 ppm               |
| Loss on drying   | Not more than 0.5%   | 0.10%                    |

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| <b>Residual solvents by GC-HS</b> |                        |            |
|-----------------------------------|------------------------|------------|
| Methanol                          | Not more than 3000 ppm | < 3000 ppm |
| <b>Heavy metals ♦</b>             |                        |            |
|                                   | Not more than 20 ppm   | < 20 ppm   |

| <b>ADDITIONAL INFORMATION</b>  |
|--|
| <p><i>Letco Medical performed identification testing of this material using a validated method</i></p> <p>CAS No. 38304-91-5</p> <p>Manufacturer Remarks: The above sample complies with the USP 43 standard.<br/>♦ As per customer requirement</p> <p>This product was manufactured by Kumar Organic Products Limited, Plot No. 60 &amp; 65, Road No. 3, Jigani Industrial Area, Jigani, Anekal Taluk, Bangalore, Karnataka 560105, India (IND)</p> |

**LETCO QA REVIEW:** \_\_\_\_\_

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