



Certificate of Analysis

Productname: Minoxidili sulfas
Number of analysis/Inspection Code: 2 / KEUR-74200B
Batchnumber: 11D05-B07-261468
Reference code / No.: 20110304
Analysed according to: MONOGR.

| Tests | Requirement | Result | Unit | Standard remark |
|--------------------------|---|---------|--------------|-------------------------------------|
| Appearance | (Almost) white, crystalline powder; odourless | Conform | | |
| Solubility | Conform | Conform | | Water, methanol and propyleneglycol |
| Identification | Conform | Conform | | IR-spectrum |
| Heavy metals | <=20 | Conform | ppm | |
| Water | <=1,0 | 0,7 | % | Karl Fischer |
| Residue on ignition | <=0,5 | <0,1 | % | |
| pH | 2,5 - 3,5 | 2,9 | | 3% <i>m/V</i> |
| Total impurities | <=1,0 | 0,7 | % | HPLC |
| Ethanol | <=8,5 | 5,4 | % | |
| Residual solvents | CPMP/ICH/283/95 | Conform | | |
| Assay Minoxidil sulphate | >=99,0 | 99,3 | % <i>m/m</i> | HPLC |

Release:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

09-06-11

Expiration: 04-2014

Conclusion: APPROVED

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