

Certificate of Analysis

Productname: Amitriptylini hydrochloridum
Number of analysis/Inspection Code: 2 / KEUR-180659B
Batchnumber: 19C08-B02-366461
Reference code / No.: 1116 / 1901746
Analysed according to: PH.EUR 9.7

| Tests | Requirement | Result | Unit | Standard remark |
|-----------------------------------|--|---------|--------------|-----------------|
| Appearance | (Almost) white powder or colorless crystals | Conform | | |
| Identification A | Conform | Conform | | IR-spectrum |
| Identification B | Conform | Conform | | Chloride |
| Appearance of solution | Clear / <B7 | Conform | | 5% <i>m/V</i> |
| Acidity or alkalinity | Conform | Conform | | |
| Related substances | Conform | Conform | | HPLC |
| Impurity B | <=0,1 | <0,05 | % | |
| Impurity A | <=0,05 | <0,05 | % | |
| Unspecified impurities | <=0,10 | <0,05 | % | |
| Total impurities | <=0,3 | <0,05 | % | |
| Loss on drying | <=0,5 | 0,1 | % | 2 h 105 °C |
| Sulphated ash | <=0,1 | 0,0 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CHMP/ICH/82260/2006 | Conform | | Data producer |
| Assay Amitriptyline hydrochloride | 99,0 - 101,0 | 100,4 | % <i>m/m</i> | Dried |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/24/20

Expiration: 02-2024

Conclusion: APPROVED

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