

## Certificate of Analysis

**Productname:** Amitriptylini hydrochloridum  
**Number of analysis/Inspection Code:** 2 / KEUR-180689B  
**Batchnumber:** 19C08-B02-367356  
**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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