

## Certificate of Analysis

**Productname:** Diltiazemi hydrochloridum  
**Number of analysis/Inspection Code:** 1 / KEUR-183890B  
**Batchnumber:** 18H09-B03-370433  
**Reference code / No.:** 4112 / AZ-0560718  
**Analysed according to:** PH.EUR 9.5

| Tests                         | Requirement                                  | Result  | Unit         | Standard remark       |
|-------------------------------|--|---------|--------------|-----------------------|
| Appearance                    | (Almost) white, crystalline powder           | Conform |              |                       |
| Identification A              | Conform                                      | Conform |              | IR-spectrum           |
| Identification D              | Conform                                      | Conform |              | Chloride              |
| Appearance of solution        | Clear and colourless                         | Conform |              | 5% <i>m/V</i>         |
| pH                            | 4,3 - 5,3                                    | 4,9     |              | 1% <i>m/V</i>         |
| Specific optical rotation     | +115 - +120                                  | +115    |              | 1% <i>m/V</i> ; dried |
| Related substances            | Conform                                      | Conform |              | HPLC                  |
| Impurity F                    | <=0,3  | < 0,05  | %            |                       |
| Unspecified impurities        | <=0,10                                       | < 0,05  | %            |                       |
| Total impurities              | <=0,3  | < 0,3   | %            |                       |
| Loss on drying                | <=0,5  | 0,3     | %            | 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 Diltiazem hydrochloride | 98,5 - 101,0                                 | 100,0   | % <i>m/m</i> | Dried                 |
| TSE/BSE-statement:            | No contamination with TSE/BSE-risk materials | Conform |              | Data producer         |

Analysis performed by the authorized laboratory Eurofins.

Release:  
Paul Hofman  
Pharmacist - Qualified Person

07/02/20

Expiration: 06-2023

Conclusion: APPROVED

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