

Certificate of Analysis

Product name: **Cetirizini dihydrochloridum**
Batch number / Weight: **21J05-B02-215609 / 10 G**
Analysed according to: **Ph. Eur.**

| Tests | Requirement | Result | Unit | Standard remark |
|----------------------------------|--|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder | Conform | | |
| Identification B | Conform | Conform | | |
| Identification D | White | Conform | | |
| Appearance of solution | Clear / colour ≤BY7 | Conform | | |
| pH | 1,2 - 1,8 | 1,33 | | |
| Related substances | Conform | Conform | | |
| Impurity A | ≤0,15 | 0,00 | % | |
| Impurity B | ≤0,15 | <0,05 | % | |
| Impurity C | ≤0,15 | 0,077 | % | |
| Impurity D | ≤0,15 | 0,00 | % | |
| Impurity E | ≤0,15 | <0,05 | % | |
| Impurity F | ≤0,15 | 0,00 | % | |
| Unspecified impurities | ≤0,10 | 0,097 | % | |
| Total impurities | ≤0,3 | 0,17 | % | |
| Loss on drying | ≤0,5 | 0,04 | % | |
| Sulphated ash | ≤0,2 | 0,03 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Cetirizine dihydrochloride | 99,0 - 101,0 | 99,99 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

18-05-2022

Expiration: 25-08-2026

Conclusion: APPROVED

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