

Certificate of Analysis

Product name: **Cetirizini dihydrochloridum**

Batch number / Weight: **22E12-B02-221470 / 10 G**

Analysed according to: **Ph. Eur. 10.8**

| 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 | 1,46 | | |
| Related substances | Conform | Conform | | |
| Impurity A | ≤0,15 | <0,05 | % | |
| Impurity B | ≤0,15 | <0,05 | % | |
| Impurity C | ≤0,15 | <0,05 | % | |
| Impurity D | ≤0,15 | <0,05 | % | |
| Impurity E | ≤0,15 | <0,05 | % | |
| Impurity F | ≤0,15 | <0,05 | % | |
| Unspecified impurities | ≤0,10 | 0,09 | % | |
| Total impurities | ≤0,3 | 0,09 | % | |
| Loss on drying | ≤0,5 | 0,03 | % | |
| Sulphated ash | ≤0,2 | 0,10 | % | |
| 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 | 100,2 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| Residual solvents | | | | |
| Methanol | ≤ 3000 | <25 | ppm | |
| Acetone | ≤ 5000 | 1665 | ppm | |
| Methylene chloride | ≤ 600 | <25 | ppm | |
| Ethyl acetate | ≤ 5000 | <25 | ppm | |
| Chloroform | ≤ 60 | <25 | ppm | |
| Toluene | ≤ 890 | <25 | ppm | |
| Dimethylformamide | <880 | <25 | ppm | |
| Benzene | ≤ 2 | <2 | ppm | |

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

17-08-2022

Expiration: 03-04-2027

Conclusion: APPROVED

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