

Certificate of Analysis

Product name: **Xylometazolini hydrochloridum**

Batch number / Weight: **22G14-B02-222167 / 10 G**

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

Number of analysis / Inspection Code **22G14-B02 / INS-22-5935**

Reference Code / No.: **V00729 / 21312028**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|--|-------------|------|-----------------|
| Appearance | (Almost) white, crystalline powder | Conform | | |
| Identification A | Conform | Conform | | |
| Identification E | White | Conform | | |
| Appearance of solution | Clear / $\leq Y_6$ | Conform | | |
| Acidity or alkalinity | Conform | 0,1 ml NaOH | | |
| Related substances | Conform | Conform | | |
| Impurity A | $\leq 0,2$ | $< 0,05$ | % | |
| Unspecified impurities | $\leq 0,10$ each | $< 0,05$ | % | |
| Total impurities | $\leq 0,5$ | 0,00 | % | |
| Loss on drying | $\leq 0,5$ | 0,08 | % | |
| Sulphated ash | $\leq 0,1$ | 0,03 | % | |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay | 99,0 - 101,0 | 100,97 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | |
| Residual solvents | | | | |
| 2-Propanol | ≤ 5000 | < 5000 | ppm | |
| Toluene | ≤ 890 | < 890 | ppm | |
| Dimethylformamide | ≤ 880 | < 880 | ppm | |

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:
Ewelina Gadzinowska
Qualified Person

25-08-2022

Expiration: 02-08-2025

Conclusion: APPROVED

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