

Certificate of Analysis

Product name: **Pseudoephedrini hydrochloridum**

Batch number / Weight: **23L28-B11-235154 / 50 G**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **23L28-B11 / INS-24-1348**

Reference Code / No.: **V01679 / 217523B**

| Tests | Requirement | Result | Unit | Standard remark |
|--------------------------------|---|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder or colourless crystals | Conform | | |
| Identification A | +61,0 - +62,5 | Conform | | |
| Identification B | Conform | Conform | | |
| Identification D | White | Conform | | |
| Appearance of solution | Clear / colourless | Conform | | |
| Acidity or alkalinity | Conform | Conform | | |
| Specific optical rotation | +61,0 - +62,5 | +61,9 | | |
| Related substances | Conform | Conform | | |
| Impurity A | <=1,0 | 0,06 | % | |
| Any other impurity | <=0,5 | <0,05 | % | |
| Sum of impurities other than A | <=1,0 | 0,00 | % | |
| Loss on drying | <=0,5 | 0,09 | % | |
| Sulphated ash | <=0,1 | 0,01 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Pseudoephedrine hydroch | 99,0 - 101,0 | 100,39 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

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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:

Agnieszka Pszczółka

Qualified Person

08-03-2024

Expiration: 30-11-2028

Conclusion: APPROVED

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