

Certificate of Analysis

Product name: **Phenylephrini hydrochloridum**

Batch number / Weight: **23F20-B01-230870 / 5 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23F20-B01 / INS-23-5425**

Reference Code / No.: **V01714 / PEH-230412**

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------------|----------------------------------------------|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder | Conform | | |
| Identification A | -43 - -47 | Conform | | |
| Identification C | Conform | Conform | | |
| Identification E | Conform | Conform | | |
| Appearance of solution | Clear and colourless | Conform | | |
| Acidity or alkalinity | Conform | Conform | | |
| | <=0,4 ml HCl (0,01M) | 0,10 ml | | |
| Specific optical rotation | -43 - -47 | -46,2 | | |
| Related substances | Conform | Conform | | |
| Impurity C | <=0,1 | 0,00 | % | |
| Impurity E | <=0,1 | 0,00 | % | |
| Unspecified impurities | <=0,10 each | <0,05 | % | |
| Total impurities | <=0,2 | 0,00 | % | |
| Sulphates | <=500 | <500 | ppm | |
| Loss on drying | <=1,0 | 0,06 | % | |
| Sulphated ash | <=0,1 | 0,00 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Phenylephrine hydrochlori | 98,5 - 101,0 | 100,36 | %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

20-09-2023

Expiration: 03-04-2026

Conclusion: APPROVED

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