

Certificate of Analysis

Product name: **Promethazini hydrochloridum**

Batch number / Weight: **21E13-B02-224519 / 10 G**

Analysed according to: **Ph.Eur.10**

Number of analysis / Inspection Code **21E13-B02 / INS-21-3008**

Reference Code / No.: **V00724 / HPHCPO108**

| Tests | Requirement | Result | Unit | Standard remark |
|--------------------------------|--|---------|------|-----------------|
| Appearance | White or faintly yellowish, crystalline powder | Conform | | |
| Melting point | about 222 | 222,8 | °C | |
| Identification A | Conform | Conform | | |
| Identification D | Conform | Conform | | |
| Solubility | acc. to Ph. Eur. | Conform | | |
| pH | 4,0 - 5,0 | 4,5 | | |
| Related substances | Conform | Conform | | |
| Impurity B | <=0,8 | 0,24 | % | |
| Impurity C | <=0,2 | 0,08 | % | |
| Impurity A | <=0,1 | <0,05 | % | |
| Impurity D | <=0,1 | <0,05 | % | |
| Unspecified impurities | <=0,10 | <0,05 | % | |
| Total impurities | <=1,2 | 0,32 | % | |
| Loss on drying | <=0,5 | 0,04 | % | |
| Sulphated ash | <=0,1 | 0,04 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Promethazine hydrochlori | 99,0 - 101,0 (dried substance) | 99,7 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

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Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail: biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl

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

26-10-2022

Expiration: 31-01-2026

Conclusion: APPROVED

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Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl