

Certificate of Analysis

Product name: **Chlorpromazini hydrochloridum**

Batch number / Weight: **21L09-B02-224374 / 25 G**

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

Number of analysis / Inspection Code **21L09-B02 / INS-22-1792**

Reference Code / No.: **V01761 / 81007E0421**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------------------|---|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder, it decomposes on exposure to air and light | Conform | | |
| Identification A | acc to Ph.Eur. | Conform | | |
| Identification C | acc to Ph.Eur. | Conform | | |
| pH | 3,5 - 4,5 | 4,34 | | |
| Impurity F | <=0,15 | <0,15 | % | |
| Related substances | Conform | Conform | | |
| Impurity B | <=0,3 | <0,05 | % | |
| Impurity C | <=0,3 | <0,05 | % | |
| Impurity D | <=0,3 | <0,05 | % | |
| Impurity A | <=0,15 | <0,05 | % | |
| Impurity E | <=0,15 | <0,05 | % | |
| Any other impurity | <=0,10 | <0,05 | % | |
| Total impurities | <=1,0 | <0,05 | % | |
| Loss on drying | <= 0,5 | 0,17 | % | |
| Sulphated ash | <= 0,1 | 0,10 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Chlorpromazine hydrochloride | 99,0 - 101,0 | 100,5 | %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 EL Spol

Release:
Ewelina Gadzinowska
Qualified Person

28-10-2022

Expiration: 30-04-2026

Conclusion: APPROVED

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