

Certificate of Analysis

Product name: **Guaifenesinum**

Batch number / Weight: **23G18-B04-231660 / 500 G**

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

Number of analysis / Inspection Code **23G18-B04 / INS-23-6281**

Reference Code / No.: **V01416 / 22GF11978**

| Tests | Requirement | Result | Unit | Standard remark |
|--------------------------------|----------------------------------------------|----------|------|-----------------|
| Appearance | (Almost) white, crystalline powder | Conform | | |
| Identification B | Conform | Conform | | |
| Appearance of solution | Clear / colourless | Conform | | |
| Acidity or alkalinity | Conform | Conform | | |
| Related substances | Conform | Conform | | |
| Impurity C | $\leq 0,1$ | $< 0,03$ | % | |
| Impurity D | $\leq 0,1$ | $< 0,03$ | % | |
| Impurity B | $\leq 0,5$ | 0,03 | % | |
| Any other impurity | $\leq 0,05$ | $< 0,03$ | % | |
| Total impurities | $\leq 0,7$ | 0,03 | % | |
| Chlorides and monochlorhydrine | ≤ 250 | < 250 | ppm | |
| Loss on drying | $\leq 0,5$ | 0,12 | % | |
| Sulphated ash | $\leq 0,1$ | 0,03 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay | 98,0 - 102,0 | 100,16 | %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

31-10-2023

Expiration: 23-11-2027

Conclusion: APPROVED

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