

## Certificate of Analysis

**Product name:** **Bromhexini hydrochloridum**

**Batch number / Weight:** **21J12-B12-232311 / 10 G**

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

**Number of analysis / Inspection Code** **21J12-B12 / INS-21-5407**

**Reference Code / No.:** **V01758 / 020L091**

| Tests                          | Requirement                                  | Result  | Unit | Standard remark |
|--------------------------------|--|---------|------|-----------------|
| Appearance                     | (Almost) white, crystalline powder           | Conform |      |                 |
| Identification A               | Conform                                      | Conform |      |                 |
| Identification C               | White  | Conform |      |                 |
| Appearance of solution         | Clear / $\leq Y_6$                           | Conform |      |                 |
| Related substances             | Conform                                      | Conform |      |                 |
| Impurity C                     | $< 0,15$                                     | 0,00    | %    |                 |
| Any impurity                   | $\leq 0,10$                                  | 0,06    | %    |                 |
| Total impurities               | $\leq 0,2$                                   | 0,1     | %    |                 |
| Loss on drying                 | $\leq 1,0$                                   | 0,1     | %    |                 |
| Sulphated ash                  | $\leq 0,1$                                   | 0,1     | %    |                 |
| Metallic residues              | CHMP/ICH/353369/2013                         | Conform |      | Data producer   |
| Residual solvents              | CPMP/ICH/82 260/06                           | Conform |      | Data producer   |
| Assay Bromhexine hydrochloride | 98,0 - 102,0                                 | 99,2    | %m/m |                 |
| TSE/BSE-statement:             | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |

fagron.pl

Fagron Services Northern Europe Sp. z o.o.  
ul. Armii Krajowej 3  
32-540 Trzebinia, Poland  
e-mail: fsne@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:  
Dominika Soltysik  
Qualified Person

28-11-2023

Expiration: 30-11-2025

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl

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