

## Certificate of Analysis

**Product name:** Loratadinum  
**Batch number / Weight:** 22D29-B04-221764 / 5 G  
**Analysed according to:** Ph. Eur. 10.8  
**Number of analysis / Inspection Code** 22D29-B04 / INS-22-7834  
**Reference Code / No.:** V01498 / BLRDE/2111020

| Tests                  | Requirement                                  | Result  | Unit | Standard remark |
|------------------------|--|---------|------|-----------------|
| Appearance             | (Almost) white, crystalline powder           | Conform |      |                 |
| Identification         | Conform                                      | Conform |      |                 |
| Appearance of solution | Clear <=BY5                                  | Conform |      |                 |
| Impurity H             | Conform                                      | <0,1    | %    |                 |
| Related substances     | Conform                                      | Conform |      |                 |
| Impurity F             | <=0,2  | <0,05   | %    |                 |
| Impurity A             | <=0,1  | <0,05   | %    |                 |
| Impurity B             | <=0,1  | <0,05   | %    |                 |
| Impurity C             | <=0,1  | <0,05   | %    |                 |
| Impurity D             | <=0,1  | <0,05   | %    |                 |
| Impurity E             | <=0,1  | <0,05   | %    |                 |
| Unspecified impurities | <=0,10                                       | <0,05   | %    |                 |
| Total impurities       | <=0,5  | <0,05   | %    |                 |
| Sulphates              | <=150  | <150    | ppm  |                 |
| Loss on drying         | <=0,5  | 0,11    | %    |                 |
| Sulphated ash          | <=0,1  | 0,02    | %    |                 |
| Metallic residues      | CHMP/ICH/353369/2013                         | Conform |      | Data producer   |
| Residual solvents      | CPMP/ICH/82 260/06                           | Conform |      |                 |
| Assay Loratadine       | 98,5 - 101,5                                 | 99,9    | %m/m |                 |
| TSE/BSE-statement:     | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |
| Residual solvents      |  |         |      |                 |
| Di-isopropyl ether     | <=500  | 44      | ppm  |                 |
| Toluene                | <=500  | <12,5   | ppm  |                 |
| Triethylamine          | <=50   | <10     | ppm  |                 |
| Tetrahydrofurane       |  | <25     | ppm  |                 |

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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

13-10-2022

Expiration: 31-10-2026

Conclusion: APPROVED

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