

Certificate of Analysis

Product name: **Tretinoinum**

Batch number / Weight: **23G06-B05-234519 / 1 G**

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

Number of analysis / Inspection Code **23G06-B05 / INS-23-5470**

Reference Code / No.: **V01406 / TRER-20221202**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|--|----------|------|-----------------|
| Appearance | yellow or light orange, crystalline powder | Conform | | |
| Identification A | Conform | Conform | | |
| Related substances | Conform | Conform | | |
| Impurity A | $\leq 0,5$ | $< 0,05$ | % | |
| Unspecified impurities | $\leq 0,2$ | 0,076 | % | |
| Total impurities | $\leq 1,0$ | 0,08 | % | |
| Loss on drying | $\leq 0,5$ | 0,01 | % | |
| Sulphated ash | $\leq 0,1$ | 0,00 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | |
| Assay | 98,0 - 102,0 | 100,48 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | |

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:
Ewelina Gadzinowska
Qualified Person

12-12-2023

Expiration: 27-11-2025

Conclusion: APPROVED

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