

Certificate of Analysis

Product name: **Tretinoinum**
Batch number / Weight: **22A22-B03-216783 / 1 G**
Analysed according to: **Ph. Eur.**

| 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 | $\leq 0,2$ | 0,06 | % | |
| Total impurities | $\leq 1,0$ | 0,13 | % | |
| 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 | 99,71 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | |
| Residual solvents | | | | |
| Ethyl acetate | ≤ 5000 | < 5000 | ppm | |

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

24-05-2022

Expiration: 01-08-2024

Conclusion: APPROVED

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