

Certificate of Analysis

Product name: **Argininum apyrogen**

Batch number / Weight: **23A12-B04-231250 / 500 G**

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

Number of analysis / Inspection Code **23A12-B04 / INS-23-1353**

Reference Code / No.: **V01167 / 21123644**

| Tests | Requirement | Result | Unit | Standard remark |
|----------------------------------|---|---------|--------|-----------------|
| Appearance | (Almost) white, crystalline powder or colourless crystals | Conform | | |
| Identification A | +25,5 - +28,5 | Conform | | |
| Identification C | Conform | Conform | | |
| Appearance of solution | Clear / <=BY6 | Conform | | |
| Specific optical rotation | +25,5 - +28,5 | +27,4 | | |
| Ninhydrin-positive substances | Conform | Conform | % | |
| Any ninhydrin-positive substance | <=0,2 | <0,05 | % | |
| Total | <=0,5 | <0,05 | % | |
| Chlorides | <=200 | <200 | ppm | |
| Sulphates | <=300 | <300 | ppm | |
| Ammonium at 570 nm | <=0,02 | <0,02 | % | |
| Iron | <=10 | <10 | ppm | |
| Loss on drying | <=0,5 | 0,20 | % | |
| Sulphated ash | <=0,1 | 0,04 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay L-Arginine | 98,5 - 101,0 | 100,36 | % | |
| Endotoxins | <=6 | <6 | IU / g | |
| 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 Own lab

Release:

Agnieszka Pszczółka

Qualified Person

27-11-2023

Expiration: 01-01-2025

Conclusion: APPROVED

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