

Certificate of Analysis

Product name: **Chinini sulfas**

Batch number / Weight: **23E04-B05-233825 / 1 KG**

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

Number of analysis / Inspection Code **23E04-B05 / INS-23-3920**

Reference Code / No.: **V01400 / 10280**

| Tests | Requirement | Result | Unit | Standard remark |
|-------------------------------|---|---------|------|-----------------|
| Appearance | white or almost white crystalline powder or fine, | Conform | | |
| Appearance | colourless needles | | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Identification C | Conform | Conform | | |
| Identification D | Conform | Conform | | |
| Identification E | Conform | Conform | | |
| Appearance of solution | Conform | Conform | | |
| pH | 5,7 - 6,6 | 6,36 | | |
| Specific optical rotation | (-237) - (-245) | -243,1 | | |
| Related substances | Conform | Conform | | |
| Impurity C | <=10 | 5,7 | % | |
| Any impurity elut.bef.quinine | <=5 | 1,8 | % | |
| Any other impurity | <=2,5 | 0,00 | % | DP |
| Loss on drying | 3,0 - 5,0 | 4,78 | % | |
| Sulphated ash | <=0,1 | 0,05 | % | |
| Assay | 99,0 - 101,0 | 100,08 | %m/m | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| 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 Fagron PL lab,CBMiA

Release:

Ewelina Gadzinowska

Qualified Person

05-10-2023

Expiration: 22-01-2028

Conclusion: APPROVED

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