

Certificate of Analysis

Product name: Acetazolamidum
Batch number / Weight: 21H04-B09-213795 / 25 G
Analysed according to: Ph. Eur.

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|--|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Appearance of solution | <=ref. susp. II / <=Y5 or BY5 | Conform | | |
| Related substances | Conform | Conform | | |
| Impurity A | <=0,15 | <0,05 | % | |
| Impurity B | <=0,15 | 0,08 | % | |
| Impurity C | <=0,15 | 0,00 | % | |
| Impurity D | <=0,15 | 0,09 | % | |
| Impurity E | <=0,15 | <0,05 | % | |
| Impurity F | <=0,15 | <0,05 | % | |
| Unspecified impurities | <=0,10 | 0,00 | % | |
| Total impurities | <=0,6 | 0,2 | % | |
| Sulphates | <=500 | Conform | ppm | |
| Loss on drying | <=0,5 | 0,2 | % | |
| Sulphated ash | <=0,1 | 0,1 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Acetazolamide | 98,5 - 101,0 | 100,5 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

09-12-2021

Expiration: 31-12-2024

Conclusion: APPROVED

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