

Certificate of Analysis

Product name: **Beclometason diprop. anh. mic.**

Batch number / Weight: **21K15-B03-217135 / 1 G**

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

| Tests | Requirement | Result | Unit | Standard remark |
|----------------------------|--|---------|------|-----------------|
| Appearance | Fine, (almost) white crystallin powder | Conform | | |
| Particle size | 99%<25 µm / 90%<10 µm | Conform | | |
| Identification A | Conform | Conform | | |
| Identification C | <=0,5 | Conform | % | |
| Specific optical rotation | +108 - +115 | +112 | ° | |
| Related substances | Conform | Conform | | |
| Impurity A | <=0,2 | <0,05 | % | |
| Impurity B | <=0,5 | <0,05 | % | |
| Impurity C | <=0,15 | <0,05 | % | |
| Impurity D | <=0,2 | <0,05 | % | |
| Impurity F | <=0,5 | <0,05 | % | |
| Impurity L | <=0,6 | <0,05 | % | |
| Impurity M | <=0,5 | <0,05 | % | |
| Impurity N | <=0,2 | <0,05 | % | |
| Unspecified impurities | <=0,10 | <0,05 | % | |
| Total impurities | <=1,5 | <0,05 | % | |
| Loss on drying | <=0,5 | 0,09 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Beclometason diprop. | 96,0 - 102,0 | 99,2 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:

Agnieszka Pszczółka

Qualified Person

14-03-2022

Expiration: 31-08-2026

Conclusion: APPROVED

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