

Certificate of Analysis

Productname: Hyoscini butylbromidum
Number of analysis/Inspection Code: 1 / KEUR-180783B
Batchnumber: 20A29-F07-367902
Reference code / No.: 1272 / 31819004
Analysed according to: PH.EUR10.0

| Tests | Requirement | Result | Unit | Standard remark |
|-----------------------------|--|---------|------|---------------------------|
| Appearance | (Almost) white, crystalline powder | Conform | | |
| Identification A | -18 - -20 | Conform | | Specific optical rotation |
| Identification C | Conform | Conform | | IR-spectrum |
| Identification F | Yellow-white | Conform | | Bromide |
| Appearance of solution | Clear / colourless | Conform | | 5%m/V |
| Acidity or alkalinity | Conform | Conform | | |
| Specific optical rotation | -18 - -20 | -19 | | 5%m/V |
| Related substances | Conform | Conform | | HPLC |
| Impurity A | <=0,15 | <0,05 | % | |
| Any other impurity | <=0,10 | 0,06 | % | |
| Total impurities | <=0,4 | 0,1 | % | |
| Loss on drying | <=2,5 | 0,1 | % | 105 °C |
| Sulphated ash | <=0,1 | 0,1 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CHMP/ICH/82260/2006 | Conform | | Data producer |
| Assay Hyoscine Butylbromide | 98,0 - 101,0 | 99,7 | %m/m | Dried |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/28/20

Expiration: 02-2024

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.