

Certificate of Analysis

Productname: Diazepamum
Number of analysis/Inspection Code: 1 / KEUR-181859B
Batchnumber: 19D17-B03-368752
Reference code / No.: 1992 / 201810090139
Analysed according to: PH.EUR 9.7

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|--|---------|------|------------------|
| Appearance | (Almost) white, crystalline powder | Conform | | |
| IR-spectrum | Conform | Conform | | |
| Related substances | Conform | Conform | | HPLC |
| Impurity A | <=0,1 | <0,05 | % | |
| Impurity B | <=0,1 | n.d. | % | |
| Impurity E | <=0,1 | <0,05 | % | |
| Unspecified impurities | <=0,10 | <0,05 | % | |
| Total impurities | <=0,2 | <0,05 | % | |
| Loss on drying | <=0,5 | <0,1 | % | 4 h 60°C; vacuum |
| 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 Diazepam | 99,0 - 101,0 | 100,1 | %m/m | Dried |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized laboratory Proxylabs.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

04/08/20

Expiration: 09-2023

Conclusion: APPROVED

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