

Certificate of Analysis

Productname: Dipyridamolum
Number of analysis/Inspection Code: 1 / KEUR-180784B
Batchnumber: 19I23-F01-367921
Reference code / No.: 1374 / 191731
Analysed according to: PH.EUR10.0

| Tests | Requirement | Result | Unit | Standard remark |
|--------------------|----------------------------------------------|---------|------|-----------------|
| Appearance | Bright yellow, crystalline powder | Conform | | |
| IR-spectrum | Conform | Conform | | |
| Related substances | Conform | Conform | | HPLC |
| Impurity A | <=0,5 | 0,1 | % | |
| Impurity B | <=0,5 | <0,05 | % | |
| Impurity C | <=0,5 | <0,05 | % | |
| Impurity D | <=0,2 | <0,05 | % | |
| Impurity E | <=0,2 | <0,05 | % | |
| Any other impurity | <=0,10 | <0,05 | % | |
| Total impurities | <=1,0 | 0,1 | % | |
| Chlorides | <=200 | Conform | ppm | |
| Loss on drying | <=0,5 | 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 Dipyridamol | 98,5 - 101,5 | 100,8 | %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

02/27/20

Expiration: 07-2024

Conclusion: APPROVED

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