

Certificate of Analysis

Productname: Riboflavinum
Number of analysis/Inspection Code: 2 / KEUR-193753B
Batchnumber: 21I07-F01-380770
Reference code / No.: 3936 / RIB2960HF
Analysed according to: PH.EUR10.5

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------|--|---------|--------------|-----------------------------------|
| Appearance | (Orange) yellow, crystalline powder | Conform | | |
| Fermentation | According to Fermentation products Ph. Eur. | Conform | | Data producer |
| Identification A | -115 - -135 | Conform | | Specific optical rotation |
| Identification B | Conform | Conform | | TLC |
| Identification C | Conform | Conform | | |
| Specific optical rotation | -115 - -135 | -130 | | 0,5% <i>m/V</i> 0.05M NaOH; dried |
| Absorbance | 223, 267, 373, 444 nm | Conform | nm | |
| Absorbance ratio | 0,31 - 0,33 | 0,32 | | E 373 / E 267 |
| Absorbance ratio | 0,36 - 0,39 | 0,38 | | E 444 / E 267 |
| Related substances | Conform | Conform | | HPLC |
| Impurity A | <=0,025 | 0,008 | % | |
| Impurity B | <=0,2 | <0,05 | % | |
| Impurity C | <=0,2 | 0,1 | % | |
| Impurity D | <=0,2 | 0,1 | % | |
| Unspecified impurities | <=0,10 | 0,07 | % | |
| Total impurities | <=0,5 | 0,2 | % | |
| Loss on drying | <=1,5 | 0,9 | % | 105°C |
| Sulphated ash | <=0,1 | 0,0 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CHMP/ICH/82260/2006 | Conform | | Data producer |
| Assay Riboflavine | 97,0 - 103,0 | 100,0 | % <i>m/m</i> | Dried |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Anthony Amoureux
Qualified Person

02/23/22

Expiration: 03-2025

Conclusion: APPROVED

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