

Certificate of Analysis

Productname: Ethylmorphini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-198718B
Batchnumber: 23D13-F03-385867
Reference code / No.: 2021 / AVL1182
Analysed according to: PH.EUR11.1

| Tests | Requirement | Result | Unit | Standard remark |
|-----------------------------------|--|--------------|------|-----------------|
| Appearance | (Almost) white crystalline powder | Conform | | |
| Identification A | Conform | Conform | | IR-spectrum |
| Identification D | Conform | Conform | | |
| Appearance of solution | Clear <=BY6 | Conform | | |
| Acidity or alkalinity | Yellow | Conform | | |
| Specific optical rotation | -102 - -105 | -104 | | Anhydrous |
| Related substances | Conform | Conform | | |
| Impurity A | <=0,2 | Not detected | % | |
| Impurity B | <=0,2 | 0,1 | % | |
| Impurity C | <=0,5 | <0,05 | % | |
| Impurity D | <=0,2 | <0,05 | % | |
| Any other impurity | <=0,1 | 0,1 | % | |
| Total impurities other than C | <=0,5 | 0,1 | % | |
| Water (Karl Fischer) | 8,0 - 10,0 | 9,5 | % | |
| Sulphated ash | <=0,1 | 0,0 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CHMP/ICH/82260/2006 | Conform | | |
| Assay Ethylmorphine hydrochloride | 99,0 - 101,0 | 100,3 | %m/m | Anhydrous |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized laboratory Proxylabs.

Manufacturer / Country : Alkaloida Chemical Company ZRT / HU
CEP :

Release:
Anthony Amoureux
Qualified Person

14-03-24

Expiration: 31-10-26

Conclusion: APPROVED

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