

Certificate of Analysis

Productname: Midazolami hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-196324B
Batchnumber: 22C29-F03-383601
Reference code / No.: 3581 / MIH/002/03/22
Analysed according to: INTERN

| Tests | Requirement | Result | Unit | Standard remark |
|-------------------------------|--|---------|-------|-----------------------|
| Appearance | Almost white crystalline powder | Conform | | |
| Identification B | Conform | Conform | | IR-spectrum |
| Identification D | Conform | Conform | | Chloride |
| Appearance of solution | Clear / <=Y6 | Conform | | 1 g / 100 ml HCl 0.1M |
| pH | 3,7 - 4,7 | 4,5 | | 0.2%/V |
| Related substances | Conform | Conform | | HPLC |
| Impurity B | <=0,2 | n.d. | % | |
| Impurity A | <=0,1 | n.d. | % | |
| Impurity G | <=0,1 | <0,05 | % | |
| Any other impurity | <=0,10 | n.d. | % | |
| Sum of impurities | <=0,3 | <0,05 | % | |
| Impurity C | <=0,1 | Conform | % | TLC |
| Loss on drying | <=0,5 | 0,5 | % | 105 °C |
| Sulphated ash | <= 0,1 | 0,0 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CHMP/ICH/82260/2006 | Conform | | |
| Assay Midazolam hydrochloride | 98,5 - 101,5 | 100,8 | %m/m | Dried |
| Endotoxins | <=0,25 | Conform | EU/mg | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized laboratory Proxylabs+Microb..

Manufacturer / Country : Ra Chem Pharma Ltd. / IN
CEP :

Release:
 Anthony Amoureux
 Qualified Person

11/21/22

Expiration: 28-02-27

Conclusion: APPROVED

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