# Certificate of Analysis

**Product name:** Vancomycini hydrochloridum
**Batch number / Weight:** 25D28-B13-014022 / 100 g
**Producer / Producer Batch Number:** Livzon Group Fuzhou Fuxing Pharma. Co., Ltd. / HAP2503005EB
**Analyzed according to:** Ph. Eur. 11.8
**Number of Analysis / Certificate no.:** 25D28-B13 / QO0020327

| | Requirement | Result | Unit | Standard remark |
|---|---|---|---|---|
| Appearance | White or almost white very hygroscopic powder | Conform | | |
| Identification | A,B | Conform | | |
| Appearance of solution | Clear | Conform | | |
| Absorbance | <=0,10 | Conform | | |
| pH | 0,00 - 7,00 | 2,76 | | |
| Vancomycin B | >=91,0 | 94,63 | % | |
| Related substances | Conform | Conform | | |
| Impurity A | <=3,0 | 0,09 | % | |
| Impurity H | <=3,0 | 1,23 | % | |
| Sum impurities B and E | <=2,0 | 0,04 | % | |
| Impurity J | <=1,6 | 0,37 | % | |
| Impurity D | <=1,5 | 0,10 | % | |
| Impurity F | <=1,5 | 0,47 | % | |
| Impurity M | <=1,5 | 0,10 | % | |
| Impurity G | <=1,2 | 0,07 | % | |
| Impurity I | <=1,2 | 0,41 | % | |
| Impurity K | <=1,2 | 0,38 | % | |
| Impurity C | <=1,0 | 0,05 | % | |
| Any other impurity RT < Vanc. | <=0,8 | 0,33 | % | |
| Any other impurity RT > Vanc. | <=0,8 | 0,55 | % | |
| no. of impurities (RT<Vanc. B) >0.30% | <=5 | 1 | | |
| no. of impurities (RT>Vanc. B) >0.30% | <=3 | 1 | | |
| Total impurities | <=9,0 | 0,00 | % | |
| Water (Karl Fischer) | <= 5,0 | 0,00 | % m/m | |
| Sulfated ash | <=1,0 | 0,20 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | DP |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | DP |
| Assay | >=1050 | 0,00 | % m/m | |
| Endotoxins | <=0,25 | < 0,13 | IU/mg | |
| TSE/BSE-statement: | EMA/410/01 guidance compliant – no contamination | Conform | | DP |
| TAMC | <=10^3 | < 10^3 | cfu/g | |

**Fagron Services Northern Europe sp. z o.o.**
ul. Armii Krajowej 3
32-540 Trzebinia
Poland

T: +48 12 3343 512
F: +48 12 3343 513
fsne@fagron.pl
www.fagron.pl

NIP: 6772437042
REGON: 381033027
KRS: 0000740604
BDO: 000601440

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|---|---|---|---|---|
| TYMC | <=10^2 | < 10^1 | cfu/g | |

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab

**Release**:

14-8-2025
Ewelina Gadzinowska
Qualified Person

**Expiration:** 16-3-2027
**Conclusion**: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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