

## Certificate of Analysis

**Product name:** Vancomycini hydrochloridum  
**Batch number / Weight:** 25H21-B15-015263 / 100 g  
**Producer / Producer Batch Number:** Livzon Group Fuzhou Fuxing Pharma. Co., Ltd. / HAP2505010EA  
**Analyzed according to:** Ph.Eur.11.8  
**Number of Analysis / Certificate no.:** 25H21-B15 / QO0022281

|                                       | Requirement                                      | Result  | Unit  | Standard remark |
|---------------------------------------|--------------------------------------------------|---------|-------|-----------------|
| Appearance                            | White or almost white very hygroscopic powder    | Conform |       |                 |
| Identification                        | A,B                                              | Conform |       |                 |
| Appearance of solution                | Clear                                            | Conform |       |                 |
| Absorbance                            | A 450 nm<=0,10;A 370 nm<=0,65                    | Conform |       |                 |
| pH                                    | 2,5-4,5                                          | 3,01    |       |                 |
| Vancomycin B                          | >=91,0                                           | 94,84   | %     |                 |
| Related substances                    | Conform                                          | Conform |       |                 |
| Impurity A                            | <=3,0                                            | <0,10   | %     |                 |
| Impurity H                            | <=3,0                                            | 1,08    | %     |                 |
| Sum of impurities B and E             | <=2,0                                            | <0,10   | %     |                 |
| Impurity J                            | <=1,6                                            | 0,37    | %     |                 |
| Impurity D                            | <=1,5                                            | <0,10   | %     |                 |
| Impurity F                            | <=1,5                                            | 0,48    | %     |                 |
| Impurity M                            | <=1,5                                            | 0,12    | %     |                 |
| Impurity G                            | <=1,2                                            | <0,10   | %     |                 |
| Impurity I                            | <=1,2                                            | 0,31    | %     |                 |
| Impurity K                            | <=1,2                                            | 0,33    | %     |                 |
| Impurity C                            | <=1,0                                            | <0,10   | %     |                 |
| Any other impurity RT < Vanc.         | <=0,8                                            | 0,34    | %     |                 |
| Any other impurity RT > Vanc.         | <=0,8                                            | 0,54    | %     |                 |
| no. of impurities (RT<Vanc. B) >0.30% | <=5                                              | Conform |       |                 |
| no. of impurities (RT>Vanc. B) >0.30% | <=3                                              | Conform |       |                 |
| Total impurities                      | <=9,0                                            | 5,2     | %     |                 |
| Water (Karl Fischer)                  | <= 5,0                                           | 2,30    | % m/m |                 |
| Sulfated ash                          | <=1,0                                            | 0,21    | %     |                 |
| Metallic residues                     | CHMP/ICH/353369/2013                             | Conform |       | DP              |
| Residual solvents                     | CPMP/ICH/82 260/06                               | Conform |       | DP              |
| Assay                                 | >=1050                                           | 1095    | % 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 |                 |

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|------|-------------|----------|-------|-----------------|
| TYMC | $\leq 10^2$ | $< 10^1$ | 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:**

27-10-2025

Agnieszka Pszczółka

Qualified Person

**Expiration:** 9-5-2027

**Conclusion:** APPROVED

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