



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 241706**

|                   |   |
|-------------------|---|
| Product:          | VANCOMYCIN HYDROCHLORIDE  |
| Lot:              | 241706  |
| Expiry date:      | 01/05/2026  |
| Reference:        | Cumple PhEur11.5  |
| Synonyms:         |   |
| Formula:          | C <sub>66</sub> H <sub>75</sub> Cl <sub>2</sub> N <sub>9</sub> O <sub>24</sub> ·HCl |
| Molecular weight: | 1486 g/mol  |

| Assay  | Result               | Specification             |   |
|--|----------------------|---------------------------|---|
| Identification                                 | Conform (A,B)        | Test PhEur (A,B)          |   |
| Organoleptic properties                        | Conform              | PhEur                     |   |
| Appearance of solution                         | Conform              | Test PhEur                |   |
| pH   | 3,0                  | 2,5 - 4,5                 |   |
| Vancomycin B (UPLC)                            | 96,1 %               | >= 91,0 %                 |   |
| Related substances (UPLC)                      | Conform              | Test PhEur                |   |
| STORE IN REFRIGERATOR (2-8°C)                  |                      |                           |   |
| Elemental impurities                           | Conform              | Test PhEur                | # |
| Water  | 2,2 %                | <= 5,0 %                  |   |
| Sulphated ashes                                | 0,0 %                | <= 1,0 %                  |   |
| Antimicrobial power                            | 1115 UI/mg           | >= 1050 UI/mg sps         |   |
| Impurity A                                     | 0,12 %               | <= 3,0 %                  |   |
| Impurity H                                     | 0,59 %               | <= 3,0 %                  |   |
| Impurities B+E                                 | < 0,10 %             | <= 2,0 %                  |   |
| Impurity J                                     | 0,48 %               | <= 1,6 %                  |   |
| Impurity D                                     | 0,18 %               | <= 1,5 %                  |   |
| Impurity F                                     | 0,38 %               | <= 1,5 %                  |   |
| Impurity M                                     | < 0,10 %             | <= 1,5 %                  |   |
| Impurity G                                     | < 0,10 %             | <= 1,2 %                  |   |
| Impurity I                                     | 0,38 %               | <= 1,2 %                  |   |
| Impurity K                                     | 0,33 %               | <= 1,2 %                  |   |
| Impurity C                                     | 0,11 %               | <= 1,0 %                  |   |
| Any other impurity eluting before Vancomycin B | 0,21% 0 Imp >=0,30 % | <=0,8% máx. 5 Imp >=0,30% |   |
| Any other impurity eluting after Vancomycin B  | 0,60% 1 Imp >=0,30 % | <=0,8% máx. 3 Imp >=0,30% |   |
| Total impurities                               | 3,9 %                | <= 9,0 %                  |   |
| Residual solvent: Ethanol                      | < 5000 ppm           | <= 5000 ppm               | # |
| Nitrosamine impurities                         | Conform              | Test PhEur                | # |

Organoleptic characteristics:

Conservation: In airtight containers. Protect from light. FRIDGE (2-8°C)

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Date of analysis: 10/10/2024

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00091 LIVZON GROUP FUZHOU FUXING PPHARMACEUTICAL CO.,LTD.,

Manufacturer batch: HAP2405002EA

| Product | Name                    | Capacity | Batch      |
|---------|-------------------------|----------|------------|
| 1193037 | VANCOMICINA CLORHIDRATO | 1 kg     | 241706-P-1 |
| 1193037 | VANCOMICINA CLORHIDRATO | 1 kg     | 241706-P-2 |
| 1193038 | VANCOMICINA CLORHIDRATO | 50 g     | 241706-I-1 |
| 1193038 | VANCOMICINA CLORHIDRATO | 50 g     | 241706-I-2 |
| 1193039 | VANCOMICINA CLORHIDRATO | 250 g    | 241706-N-1 |
| 1193039 | VANCOMICINA CLORHIDRATO | 250 g    | 241706-N-2 |

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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