



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233907

| | |
|-------------------|---|
| Product: | VANCOMYCIN HYDROCHLORIDE |
| Lot: | 233907 |
| Expiry date: | 28/09/2025 |
| Reference: | Cumple PhEur11.3 |
| Synonyms: | |
| Formula: | C ₆₆ H ₇₅ Cl ₂ N ₉ O ₂₄ ·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 | 2,8 | 2,5 - 4,5 | |
| Vancomycin B (UPLC) | 95,5 % | >= 91,0 % | |
| Related substances (UPLC) | Conform | Test PhEur | |
| STORE IN REFRIGERATOR (2-8°C) | | | |
| Elemental impurities | Conform | Test PhEur | # |
| Water | 2,0 % | <= 5,0 % | |
| Sulphated ashes | 0,05 % | <= 1,0 % | |
| Antimicrobial power | 1088 UI/mg sps | >= 1050 UI/mg sps | |
| Impurity A | 0,2 % | <= 3,0 % | |
| Impurity H | 1,1 % | <= 3,0 % | |
| Impurities B+E | < 0,10 % | <= 2,0 % | |
| Impurity J | 0,4 % | <= 1,6 % | |
| Impurity D | 0,1 % | <= 1,5 % | |
| Impurity F | 0,3 % | <= 1,5 % | |
| Impurity M | < 0,10 % | <= 1,5 % | |
| Impurity G | 0,1 % | <= 1,2 % | |
| Impurity I | 0,4 % | <= 1,2 % | |
| Impurity K | 0,4 % | <= 1,2 % | |
| Impurity C | 0,1 % | <= 1,0 % | |
| Any other impurity eluting before Vancomycin B | 0,3%;1 imp >=0,30 % | <=0,8% máx. 5 Imp >=0,30% | |
| Any other impurity eluting after Vancomycin B | 0,5 %;1 imp >=0,30 % | <=0,8% máx. 3 Imp >=0,30% | |
| Total impurities | 4,5 % | <= 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)

Date of analysis: 09/02/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00091

Manufacturer batch: HAP2309014EA

| Product | Name | Capacity | Batch |
|---------|-------------------------|----------|------------|
| 1193030 | VANCOMICINA CLORHIDRATO | 5 kg | 233907-Q-1 |
| 1193037 | VANCOMICINA CLORHIDRATO | 1 kg | 233907-P-1 |
| 1193038 | VANCOMICINA CLORHIDRATO | 50 g | 233907-I-1 |
| 1193039 | VANCOMICINA CLORHIDRATO | 250 g | 233907-N-1 |

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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