



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251550

| | |
|--------------------|--|
| Product: | METFORMIN HYDROCHLORIDE |
| Lot: | 251550 |
| Expiry date: | 30/04/2030 |
| Reference: | Cumple PhEur11.8 |
| Synonyms: | 1,1-Dimetilbiguanida clorhidrato. |
| Formule: | C ₄ H ₁₁ N ₅ ·HCl |
| Poids moléculaire: | 165,6 g/mol |

| Assay | Result | Specification | |
|--|---------------|------------------|---|
| Identification | Conform (B,E) | Test PhEur (B,E) | |
| Organoleptic properties | Conform | PhEur | |
| Appearance of the S solution (10% water) | Conform | | |
| Elemental impurities | Conform | Test PhEur | # |
| Related substances (HPLC) | Conform | | |
| Loss on drying | 0,06 % | <= 0,5 % | |
| Sulphated ashes | 0,02 % | <= 0,1% | |
| ASSAY (anhydrous vehicle PFP) | 100,9 % | 98,5-101,0% | |
| Impurity F | 0,02 % | <= 0,05 % | |
| Impurity A | < 0,02 % | <= 0,02 % | |
| Unspecified Impurities | < 0,03 % | <= 0,05 % | |
| Total impurities | < 0,2 % | <= 0,2 % | |
| Residual solvent: Methanol | < 1000 ppm | <= 1000 ppm | # |
| Residual solvent: xylene | < 500 ppm | <= 500 ppm | # |

Organoleptic characteristics: White or almost white crystals. Freely soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in acetone and in methylene chloride.

Conservation: In tightly closed containers. Protect from moisture.

Date of analysis: 08/08/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00231 WANBURY LIMITED

Manufacturer batch: ME07980525

| Produit | Nom | Capacité | Lot |
|---------|------------------------|----------|------------|
| 1160111 | METFORMINA CLORHIDRATO | 100 g | 251550-J-2 |
| 1160111 | METFORMINA CLORHIDRATO | 100 g | 251550-J-3 |
| 1160114 | METFORMINA CLORHIDRATO | 1 kg | 251550-P-2 |

| | | | |
|---------|------------------------------|-------|------------|
| 1160114 | METFORMINA CLORHIDRATO | 1 kg | 251550-P-3 |
| 1160115 | METFORMINA CLORHIDRATO | 5 kg | 251550-Q-1 |
| 1160115 | METFORMINA CLORHIDRATO | 5 kg | 251550-Q-2 |
| 1160116 | METFORMINA CLORHIDRATO | 25 kg | 251550-T-1 |
| 1160116 | METFORMINA CLORHIDRATO | 25 kg | 251550-T-2 |
| 1160116 | METFORMINA CLORHIDRATO | 25 kg | 251550-T-3 |
| 1370035 | METFORMINA CLORHIDRATO (FLB) | 1 kg | 251550-P-1 |
| 1370174 | METFORMINA CLORHIDRATO (FLB) | 100 g | 251550-J-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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