



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 233336**

|                    |                                   |
|--------------------|-----------------------------------|
| Product:           | METFORMIN HYDROCHLORIDE           |
| Lot:               | 233336                            |
| Expiry date:       | 30/12/2027                        |
| Reference:         | Cumple PhEur11.2                  |
| Synonyms:          | 1,1-Dimetilbiguanida clorhidrato. |
| Formule:           | C4H11N5·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                           | 0,00 %        | <= 0,5 %         |   |
| Sulphated ashes                          | 0,02 %        | <= 0,1%          |   |
| ASSAY (anhydrous vehicle PFP)            | 100,9 %       | 98,5-101,0%      |   |
| Impurity F                               | 0,01 %        | <= 0,05 %        |   |
| Impurity A                               | 0,001 %       | <= 0,02 %        |   |
| Unspecified Impurities                   | < 0,03 %      | <= 0,05 %        |   |
| Total impurities                         | < 0,03 %      | <= 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: 12/09/2023

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00231 WANBURY LIMITED

Manufacturer batch: ME01120123

| Produit | Nom                    | Capacité | Lot        |
|---------|------------------------|----------|------------|
| 1160111 | METFORMINA CLORHIDRATO | 100 g    | 233336-J-1 |
| 1160111 | METFORMINA CLORHIDRATO | 100 g    | 233336-J-3 |
| 1160114 | METFORMINA CLORHIDRATO | 1 kg     | 233336-P-1 |

|         |                              |       |            |
|---------|------------------------------|-------|------------|
| 1160114 | METFORMINA CLORHIDRATO       | 1 kg  | 233336-P-2 |
| 1160114 | METFORMINA CLORHIDRATO       | 1 kg  | 233336-P-4 |
| 1160114 | METFORMINA CLORHIDRATO       | 1 kg  | 233336-P-5 |
| 1160115 | METFORMINA CLORHIDRATO       | 5 kg  | 233336-Q-1 |
| 1160115 | METFORMINA CLORHIDRATO       | 5 kg  | 233336-Q-2 |
| 1160115 | METFORMINA CLORHIDRATO       | 5 kg  | 233336-Q-3 |
| 1160116 | METFORMINA CLORHIDRATO       | 25 kg | 233336-T-1 |
| 1160116 | METFORMINA CLORHIDRATO       | 25 kg | 233336-T-2 |
| 1160116 | METFORMINA CLORHIDRATO       | 25 kg | 233336-T-3 |
| 1160116 | METFORMINA CLORHIDRATO       | 25 kg | 233336-T-4 |
| 1160116 | METFORMINA CLORHIDRATO       | 25 kg | 233336-T-5 |
| 1370035 | METFORMINA CLORHIDRATO (FLB) | 1 kg  | 233336-P-3 |
| 1370174 | METFORMINA CLORHIDRATO (FLB) | 100 g | 233336-J-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

ACOFARMA DISTRIBUCIÓN, S.A.  
C/ Llobregat, 20 - 08223 Terrassa (Barcelona)  
Tel./ 93-736.00.88  
[www.acofarma.com](http://www.acofarma.com)

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