



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 220795**

Product:	METFORMIN HYDROCHLORIDE
Lot:	220795
Expiry date:	01/10/2026
Reference:	Cumple PhEur10.6
Synonyms:	1,1-Dimetilbiguanida clorhidrato.
Formula:	C <sub>4</sub> H <sub>11</sub> N <sub>5</sub> ·HCl
Molecular weight:	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	0,03 %	<= 0,5 %	
Sulphated ashes	0,02 %	<= 0,1%	
ASSAY (anhydrous vehicle PFP)	99,7 %	98,5-101,0%	
Impurity F	0,01 %	<= 0,05 %	
Impurity A	0,00 %	<= 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: 25/02/2022

Judgement:  
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00231 WANBURY LIMITED

Manufacturer batch: ME12741121

Product	Name	Capacity	Batch
1160111	METFORMINA CLORHIDRATO	100 g	220795-J-1
1160111	METFORMINA CLORHIDRATO	100 g	220795-J-3
1160111	METFORMINA CLORHIDRATO	100 g	220795-J-4

1160114	METFORMINA CLORHIDRATO	1 kg	220795-P-2
1160114	METFORMINA CLORHIDRATO	1 kg	220795-P-6
1160116	METFORMINA CLORHIDRATO	25 kg	220795-T-1
1160116	METFORMINA CLORHIDRATO	25 kg	220795-T-2
1160116	METFORMINA CLORHIDRATO	25 kg	220795-T-3
1370035	METFORMINA CLORHIDRATO (FLB)	1 kg	220795-P-1
1370035	METFORMINA CLORHIDRATO (FLB)	1 kg	220795-P-3
1370035	METFORMINA CLORHIDRATO (FLB)	1 kg	220795-P-4
1370035	METFORMINA CLORHIDRATO (FLB)	1 kg	220795-P-5
1370037	METFORMINA CLORHIDRATO (FLB) (INACTIVO)	250 g	220795-N-1
1370174	METFORMINA CLORHIDRATO (FLB)	100 g	220795-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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