



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 215958

Product:	METFORMIN HYDROCHLORIDE
Lot:	215958
Expiry date:	01/07/2026
Reference:	Cumple PhEur10.5
Synonyms:	1,1-Dimetilbiguanida clorhidrato.
Formula:	C ₄ H ₁₁ N ₅ ·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	0,09 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1%	
ASSAY (anhydrous vehicle PFP)	100,1 %	98,5-101,0%	
Impurity F	0,013 %	<= 0,05 %	
Impurity A	0,0005 %	<= 0,02 %	
Unspecified Impurities	<= 0,03 %	<= 0,05 %	
Total impurities	0,0005 %	<= 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: 10/11/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00231 WANBURY LIMITED

Manufacturer batch: ME08980821

Product	Name	Capacity	Batch
1160111	METFORMINA CLORHIDRATO	100 g	215958-J-1
1160114	METFORMINA CLORHIDRATO	1 kg	215958-P-2
1160116	METFORMINA CLORHIDRATO	25 g	215958-T-1

1160116	METFORMINA CLORHIDRATO	25 kg	215958-T-2
1370035	METFORMINA CLORHIDRATO (FLB)	1 kg	215958-P-1
1370036	METFORMINA CLORHIDRATO (FLB) (INACTIVO)	500 g	215958-O-1
1370037	METFORMINA CLORHIDRATO (FLB) (INACTIVO)	250 g	215958-N-1
1370037	METFORMINA CLORHIDRATO (FLB) (INACTIVO)	250 g	215958-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

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

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