



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 210738

Product:	METFORMIN HYDROCHLORIDE
Lot:	210738
Expiry date:	30/11/2025
Reference:	Cumple PhEur10.3
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	0,08 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1%	
ASSAY (anhydrous vehicle PFP)	100,5 %	98,5-101,0%	
Impurity F	0,02 %	<= 0,05 %	
Impurity A	0,002 %	<= 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: 05/03/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00231 WANBURY LIMITED

Manufacturer batch: ME10501220

Product	Name	Capacity	Batch
1160114	METFORMINA CLORHIDRATO	1 kg	210738-P-3
1160114	METFORMINA CLORHIDRATO	1 kg	210738-P-4
1160116	METFORMINA CLORHIDRATO	25 kg	210738-T-1

1370035	METFORMINA CLORHIDRATO (FLB)	1 kg	210738-P-1
1370036	METFORMINA CLORHIDRATO (FLB) (INACTIVO)	500 g	210738-O-1
1370036	METFORMINA CLORHIDRATO (FLB) (INACTIVO)	500 g	210738-O-2
1370037	METFORMINA CLORHIDRATO (FLB) (INACTIVO)	250 g	210738-N-1
1370037	METFORMINA CLORHIDRATO (FLB) (INACTIVO)	250 g	210738-N-2
1370174	METFORMINA CLORHIDRATO (FLB)	100 g	210738-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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