



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.
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	0,00 %	<= 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

Product	Name	Capacity	Batch
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

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