

2005000177



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Certificate of Analysis

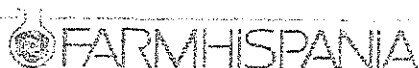
Product:	METFORMIN HYDROCHLORIDE		
Batch No.:	3103800112	LIMS lot No.:	2274
Manufacturing date:	Mar/2020	Re-test date:	Mar/2025
Analysis date:	06/Mar/2020		

TESTS	SPECIFICATIONS	RESULTS
Description		
Color	White or almost white	White
Appearance	Crystals	Crystals
Identification		
IR Spectra (KBr)	Similar to standard	Conforms
Chlorides	Presence of chlorides	Conforms
Appearance of solution (10 % in water)		
Clarity	Clear	Clear
Color	Colorless	Colorless
Melting point	222 °C to 226 °C	223 °C
Loss on drying (105 °C)	≤ 0.5 %	0.0 %
Residue on ignition	≤ 0.1 %	0.04 %
Heavy metals	≤ 10 ppm	< 10 ppm
Impurity F (HPLC)	≤ 0.05 %	<0.003 %
Related substances (HPLC)		
Impurity A	≤ 0.02 %	0.002 %
Any unknown impurity (Max.)	≤ 0.05 %	<0.02 %
Total impurities	≤ 0.2 %	<0.02 %
Assay (On dried substance)	98.5 % to 101.0 %	99.6 %
Ortho-Xylene (Residual Solvents, GC)	≤ 500 ppm	Not detected (Validated result)
Particle size		
Below 500 µm	Not less than 95 %	99 %
Below 250 µm	Not less than 40 %	62 %
Below 200 µm	Not less than 15 %	53 %
Density		
Bulk density	Between 0.50 g/mL and 0.80 g/mL	0.65 g/mL
Tapped density	Between 0.75 g/mL and 1.00 g/mL	0.90 g/mL

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None of the products will be supplied to countries in which this could be in conflict with existing patents. However, the final responsibility lies exclusively with the buyer.



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Remarks: The product complies with Ph. Eur. current edition. (R1-CEP 1999-183-Rev 04).

Issued by Quality Control

Approved by Quality Control

Release by Quality Assurance

Name: Begonia Gracia Vigara

Name: Lluís Teixidó Matau

Name: Vanessa Sucas Panadero

Date: 10/Mar/2020

Date: 08/Mar/2020

Date: 09/Mar/2020

This document has been electronically signed

Print Date: 10/Mar/2020

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