

METFORMINA HCL (EUR. PH.)

PRODUCT CODE: 1278	CAS Nº: 1115-70-4	ANALYSIS Nº: 208/22
MANUFACTURER BATCH: 2021MPC0455	CERTIFICATE ID: 35.928	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/09/2021	
METAPH BATCH: 0141221	EXPIRY DATE: 30/08/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystals	White crystals (*)
Solubility	Freely soluble in water, slightly soluble in ethanol (96 %), practically insoluble in acetone and in methylene chloride	Complies
Identification B	Complies	Complies (*)
Identification E	Complies	Complies (*)
Appearance of solution	Clear and colourless	Complies
Impurity F	=< 0.05 %	0.03 %
Related substances		
Impurity A	=< 0.02 %	0.004 %
Unspecified impurities	=< 0.05 %	0.038 %
Total impurities	=< 0.2 %	0.073 %
Loss on drying	=< 0.5 %	0.08 % (*)
Sulfated ash	=< 0.1 %	< 0.1 % (*)
Assay	98.5 - 101.0 %	100.97 % (*)
Residual solvents [In-house]		(**)
Methanol	=< 3000 ppm	26 ppm
Particle size		
100 % through 100 mesh	Complies	Complies

COMPLIES WITH

European Pharmacopoeia 10.1

REMARKS

Metformin HCl is subjected to the requirements of the ICH Q3D "Elemental Impurities" and the requirements of the EMA/CHMP/ICH/82260/2006 guideline.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

(*) Data controlled by Metapharmaceutical Industrial SL.

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Store in a dry, cool and well-ventilated place. Keep away from sources of heat.

Analysis date: 28/09/2022
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001109
 AURO LABORATORIES LIMITED
 Manufacturing Unit: K-56, M.I.D.C. TARAPUR
 401506 Dist. Thane
 MAHARASHTRA(India)

