

METFORMINA HCL (EUR. PH.)

PRODUCT CODE: 1278	CAS Nº: 1115-70-4	ANALYSIS Nº: 204/23
MANUFACTURER BATCH: 2022MPC0473	CERTIFICATE ID: 39.160	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/09/2022	
METAPH BATCH: 0110723	EXPIRY DATE: 30/08/2027	

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	Clear and colourless
Impurity F	=< 0.05 %	0.01 %
Related substances		
Impurity A	=< 0.02 %	0.002 %
Unspecified impurities	=< 0.05 %	0.05 %
Total impurities	=< 0.2 %	0.05 %
Loss on drying	=< 0.5 %	0.1 %
Sulfated ash	=< 0.1 %	0.04 %
Assay	98.5 - 101.0 %	100.6 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Metformine Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data adapted from the manufacturer's certificate of analysis.

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.

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

All methods of analysis are validated by official pharmacopoeias 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: 09/10/2023
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001109
 AURO LABORATORIES LIMITED
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 401506 Dist. Thane
 MAHARASHTRA(India)

