

METOCLOPRAMIDA HCL MONOHIDRATO (EUR. PH.)

PRODUCT CODE: 002946	CAS Nº: 54143-57-6	ANALYSIS Nº: 151/23
MANUFACTURER BATCH: 22014M1RII	CERTIFICATE ID: 38.502	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/12/2022	
METAPH BATCH: 0340523	EXPIRY DATE: 30/11/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or crystals	White crystalline powder
Solubility	Very soluble in water, freely soluble in ethanol (96 %), sparingly soluble in methylene chloride	Complies (*)
Melting point	About 183 °C, with decomposition	184 °C (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification D	Complies	Complies
pH	4.5 - 6.0	4.8
Appearance of solution	Clear and colourless	Clear and colourless
Impurity E	=< 0.5 %	< 0.5 %
Related substances		
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.2 %	< 0.05 %
Water	4.5 - 5.5 %	5.2 %
Sulfated ash	=< 0.1 %	0.07 %
Assay	99.0 - 101.0 %	100.8 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Metoclopramide Hydrochloride Monohydrate 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

Keep tightly closed, in a dry and cool place and protected from the light.

Analysis date: 20/07/2023
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000356
 IPCA LABORATORIES LIMITED
 A-1/7 & A-1/8 Phase a, GIDC
 396195 Vapi
 (India)

