

TECHNICAL DATA SHEET

002946-TDS-ENG-2026

METOCLOPRAMIDA HCL MONOHIDRATO (EUR. PH.)		
DESCRIPTION DCI: METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE		DESCRIPTION DOE: METOCLOPRAMIDA HIDROCLORURO M
CAS Nº: 54143-57-6	EC Nº: 641-713-2	AEMPS CODE: 1958CM
MOL. WEIGHT: 354.27	MOL. FORMULA: C ₁₄ H ₂₅ Cl ₂ N ₃ O ₃	ARTICLE CODE: 002946

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

COMPLIES WITH

European Pharmacopoeia 12.2

STORAGE

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

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.

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.

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