

TECHNICAL DATA SHEET

002687-TDS-ENG-2026

METOCARBAMOL (USP)		
DESCRIPTION DCI: methocarbamol		DESCRIPTION DOE: METOCARBAMOL
CAS N°: 532-03-6	EC N°: 208-524-3	AEMPS CODE: 1957A
MOL. WEIGHT: 241,24	MOL. FORMULA: C ₁₁ H ₁₅ NO ₅	ARTICLE CODE: 002687

ATTRIBUTES	SHOULD BE
Appearance	White powder, odorless or having a slight characteristic odor
Identification A	Complies
Identification B	Complies
Melting point	About 94 °C
Assay	98.5 - 101.5 %
Organic Impurities	
Guaifenesin	=< 0.15 %
Methocarbamol isomer	=< 0.05 %
Methocarbamol dioxolone	=< 0.05 %
Any individual impurity	=< 0.05 %
Total impurities	=< 1.0 %
Loss on drying	=< 0.5 %
Residue on ignition	=< 0.1 %

COMPLIES WITH

USP 2026

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

Methocarbamol is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.