



TECHNICAL DATA SHEET

1381-TDS-ENG-2025

PARACETAMOL CRISTAL (EUR. PH.)		
DESCRIPTION DCI: PARACETAMOL		DESCRIPTION DOE: PARACETAMOL
CAS Nº: 103-90-2	EC Nº: 203-157-5	AEMPS CODE: 12A
MOL. WEIGHT: 151,16	MOL. FORMULA: C ₈ H ₉ NO ₂	ARTICLE CODE: 1381

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Sparingly soluble in water, freely soluble in ethanol (96 %), very slightly soluble in methylene chloride
Identification B	Complies
Related substances	
Impurity K	=< 50 ppm
Impurity J	=< 10 ppm
Unspecified impurities	=< 0.05 %
Total impurities	=< 0.2 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed in a fresh, dry, well-ventilated place and protected from light.

REMARKS

PARACETAMOL 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.