

TECHNICAL DATA SHEET

1166-TDS-ENG-2026

KETOPROFEN (EUR. PH.)		
DESCRIPTION DCI: ketoprofen		DESCRIPTION DOE: KETOPROFENO
CAS Nº: 22071-15-4	EC Nº: 244-759-8	AEMPS CODE: 1810A
MOL. WEIGHT: 254,29	MOL. FORMULA: C16H14O3	ARTICLE CODE: 1166

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone, in ethanol (96 per cent) and in methylene chloride
Identification C	Complies
Appearance of solution	Clear and not more intensely coloured than reference solution Y6
Related substances	
Impurity A	=< 0.10 %
Impurity C	=< 0.10 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.4 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 100.5 %

COMPLIES WITH

European Pharmacopoeia 12.1

STORAGE

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

REMARKS

Ketoprofen 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.