



TECHNICAL DATA SHEET

002799-TDS-ENG-2021

MELOXICAM		
DESCRIPTION DCI: MELOXICAM		DESCRIPTION DOE: MELOXICAM
CAS Nº: 71125-38-7	EC Nº: 615-253-8	AEMPS CODE: 7153A
MOL. WEIGHT: 351.40	MOL. FORMULA: C ₁₄ H ₁₃ N ₃ O ₄ S ₂	ARTICLE CODE: 002799

ATTRIBUTES	SHOULD BE
Appearance	Pale yellow powder
Solubility	Practically insoluble in water, soluble in dimethylformamide, very slightly soluble in ethanol (96 %)
Identification	Complies
Related substances	
Impurity A at 350 nm	=< 0.1 %
Impurity B at 260 nm	=< 0.1 %
Impurity C at 350 nm	=< 0.05 %
Impurity D at 350 nm	=< 0.05 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.3 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %
Residual solvents	
Methanol	=< 3000 ppm
o-Xylene	=< 196 ppm

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

Preserve in well closed container, protected from light.

REMARKS

Meloxicam 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.