METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

002852-TDS-ENG-2024

IBUPROFENO (EUR. PH.)		
DESCRIPTION DCI: IBUPROFEN	DESCRIPTION DOE: IBUPROFENO	
CAS Nº: 15687-27-1	EC Nº: 239-784-6	AEMPS CODE: 1769A
MOL. WEIGHT: 206,3	MOL. FORMULA: C13H18O2	ARTICLE CODE: 002852

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or colourless crystals
Solubility	Practically insoluble in water, freely soluble in acetone, in methanol and in methylene chloride. It dissolves in dilute solutions of alkali hydroxides and carbonates
Identification A	Complies
Identification C	Complies
Melting point	75 - 78 ºC
Appearance of solution	Clear and colourless
Optical rotation	-0.05º - +0.05º
Related substances	
Impurity A	=< 0.15 %
Impurity J	=< 0.15 %
Impurity N	=< 0.15 %
Unspecified impurities	=< 0.05 %
Total impurities	=< 0.20 %
Impurity F	=< 0.10 %
Loss on drying	=< 0.50 %
Sulfated ash	=< 0.10 %
Assay	98.5 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep tightly closed, in a dry and cool place.

REMARKS

Ibuprofen 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.