



TECHNICAL DATA SHEET

46433078-TDS-ENG-2024

MELATONINA (EUR. PH.)		
DESCRIPTION DCI: MELATONIN		DESCRIPTION DOE: MELATONINA
CAS N°: 73-31-4	EC N°: 200-797-7	AEMPS CODE: 90496A
MOL. WEIGHT: 232,28	MOL. FORMULA: C ₁₃ H ₁₆ N ₂ O ₂	ARTICLE CODE: 46433078

ATTRIBUTES	SHOULD BE
Appearance	White to slightly yellowish powder
Solubility	Slightly soluble in water, soluble in ethanol (96 %), sparingly soluble in ethyl acetate and practically insoluble in heptane
Identification	Complies
Related substances	
Unspecified impurities	=< 0,10 %
Total impurities	=< 0,5 %
Water	=< 0,3 %
Sulfated ash	=< 0,1 %
Assay	98,0 - 102,0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

REMARKS

Melatonin 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.