

MELATONINA (EUR. PH.)

PRODUCT CODE: 46433078	CAS Nº: 73-31-4	ANALYSIS Nº: 243/24
MANUFACTURER BATCH: MTN20240801	CERTIFICATE ID: 43.592	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 08/08/2024	
METAPH BATCH: 0260924	EXPIRY DATE: 07/08/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White to slightly yellowish powder	White to slightly yellowish powder
Solubility	Slightly soluble in water, soluble in ethanol (96 %), sparingly soluble in ethyl acetate and practically insoluble in heptane	Complies (*)
Identification	Complies	Complies
Related substances		
Unspecified impurities	=< 0.10 %	0.05 % (RT = 15.91 min)
Total impurities	=< 0.5 %	0.05 %
Water	=< 0.3 %	0.1 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	98.0 - 102.0 %	100.8 %

COMPLIES WITH

European Pharmacopoeia 11.0

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".

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 15/10/2024
 Signature: Albert Sanchez Lopez (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000349

