

黄冈赛康药业有限公司

HUANGGANG SAIKANG PHARMACEUTICAL CO.,LTD

Add: No. 1 Baihewan Road, Huanggang Chemical Industry Park, Huangzhou District, Huanggang City, Hubei Province Tel:86-713-8667500

CERTIFICATE OF ANALYSIS



品名: 褪黑素
PRODUCT NAME: Melatonin
包装: 25 千克/桶
PACKING: 25KG/DRUM
生产日期: 2024. 07. 28
MANUFACTURING DATE: JUL. 28, 2024

批号: 20240703
BATCH NO.: 20240703
批重量: 200KG
BATCH WEIGHT: 200KG
有效期: 2027. 07. 27
EXPIRY DATE: JUL. 27, 2027

性状: 白色或类白色结晶粉末, 溶于乙醇, 微溶于水。

Characteristics: A white or off-white crystalline powder. Soluble in alcohol, Slightly soluble in water.

储藏条件: 避光、密闭保存。

Storage: Store in a well-closed container protected from light.

项目 ITEMS	规格说明 SPECIFICATION	实测数据 RESULTS
鉴别 IDENTIFICATION		
A、INFRARED ABSORPTION	POSITIVE	POSITIVE
B、ULTRAVIOLET ABSORPTION	POSITIVE	POSITIVE
C、HPLC IDENTIFICATION TEST	POSITIVE	POSITIVE
干燥失重 LOSS ON DRYING	1.0% MAX	0.21%
炽灼残渣 RESIDUE ON IGNITION	0.1% MAX	0.06%
熔点 MELTING POINT	116.0-120.0°C	117.7-118.8°C
氯化物或硫酸盐 CHLORIDE AND SULFATE	≤0.02%	PASS
重金属 HEAVY METALS	As ≤ 1PPM Cd ≤ 1PPM Hg ≤ 0.1PPM Pb ≤ 1PPM	PASS
有关物质 RELATED COMPOUNDS	INDIVIDUAL IMPURITIES ≤ 0.1% TOTAL IMPURITIES ≤ 1.0%	0.01% 0.03%
含量 ASSAY	98.5~101.5%	100.0%

结论: 符合药典 USP43 标准。

CONCLUSION: CONFORM WITH THE REQUIREMENT OF USP43 STANDARD.

质保部主管:

QA MANAGER:

化验员:

ANALYST:

林玲