

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. 14

MANUFACTURING DATE: JUL. 14, 2024

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.

批号: 20240702

BATCH NO.: 20240702

批重量: 425KG

BATCH WEIGHT: 425KG

有效期: 2027. 07. 13

EXPIRY DATE: JUL. 13, 2027

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. 14%
炽灼残渣 RESIDUE ON IGNITION	0. 1% MAX	0. 02%
熔点 MELTING POINT	116. 0-120. 0°C	117. 2-118. 4°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. 02% 0. 03%
含量 ASSAY	98. 5~101. 5%	100. 1%

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