



Inner Mongolia Kangpu Pharmaceutical Co., Ltd.

ADD: Intersection East of No. 1 North Street and No.1 East Road, Development Test Zone of Transformation of
Resource-dependent City of Chifeng, Yuanbaoshan District, Chifeng, Inner Mongolia, China.
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质量检验报告

CERTIFICATE OF ANALYSIS

报告号/ Report No: YC250710-01

生产日期/Manufacturing Date: 2025.06.30

产品名称/Product Name	舒必利/Sulpiride	包装/Packing	25kg/drum
批号/Lot. No	S2506003	数量/Quantity	470.8kg
检验项目/Test Items	全检/Full test	检验日期/Test Date	2025.07.10
检品来源/Sample From	原料药车间/API Workshop	报告日期/Report Date	2025.07.23
检验依据/Inspection Basis	EP 标准/EP 11.0	有效期至/Exp. Date	2029.06.29
项目/Test Item	接受标准/Specification	检验结果/Result	
性状/Appearance	白色或类白色结晶性粉末。几乎不溶于水，略溶于甲醇，微溶于乙醇（96%）和二氯甲烷。溶于矿物酸和碱氢氧化物的稀溶液。/White or almost white, crystalline powder; Practically insoluble in water, sparingly soluble in methanol, slightly soluble in ethanol (96 per cent) and in methylene chloride. It dissolves in dilute solutions of mineral acids and alkali hydroxides	符合规定/Complies	
鉴别/Identification	本品的红外光吸收图谱应与对照品的图谱一致。/The infrared absorption spectrum of the substance to be examined should be correspond to the spectrum of sulpiride CRS.	符合规定/Complies	
溶液澄清度/ Appearance of solution	溶液应澄清无色，或颜色不得浓于对照溶液 Y ₆ The solution is clear, or not more intensely coloured than reference solution Y ₆ .	符合规定/Complies	
杂质 A / Impurity A	Not more than 0.1%	符合规定/Complies	
有关物质/Related Substances	未知杂质 / Unspecified impurities: ≤0.10%	未检出 / Not detected	
	总杂质 / Total: ≤0.3%	未检出 / Not detected	
残留溶剂/Residual solvent	乙醇/Ethanol ≤0.5%	0.04%	
	乙二醇/Ethylene glycol ≤0.062%	未检出 / Not detected	
	甲醇/Methanol ≤0.3%	0.0449%	
氯化物/Chlorides	不得过 0.01% / maximum 0.01 %	符合规定/Complies	
铁盐/Iron	不得过 0.001% / maximum 0.001 %	符合规定/Complies	
干燥失重/Loss on drying	不得过 0.5% / maximum 0.5 %	0.02%	
炽灼残渣/Sulfated ash	不得过 0.1% / maximum 0.1 %	<0.1%	
粒径/PSD	D90<20μm	6.9μm	
含量/Assay	98.5 %~101.0% (按干燥品计/Calculated by dried substance)	99.9%	

结论：本品按 EP11.0 标准检验，结果符合规定。

Conclusion: The test results meet the requirements of EP 11.0.

检验人

Analyst 花月 张

化验室负责人

QC supervisor 张明

质量部长

QA supervisor 张明

Free sample

OK,

EWK EIT

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JH