



检验报告书

CERTIFICATE OF ANALYSIS

品名 Product Name		雌三醇(粗品) Estrinol	包装规格 Packing	0.5kg/Bag
批号 Batch No.		30321701002	生产日期 Mfg. Date	2017.01.08
数量 Quantity		0.5kg	复验日期 Retest Date	2019.01.07
检验依据 Analysis Reference		According to USP39		
检验项目和结果 Items And Results				
检验项目 Items		标准 Specifications	检测结果 Test results	
01	外观 Appearance	白色至类白色结晶性粉末 White to off-white crystalline powder	白色结晶性粉末 Off-white crystalline powder	
02	溶解度 Solubility	不溶于水, 略溶于 96%乙醇、溶于丙酮、氯仿、二氧六环、乙醚、植物油。 Insoluble in water, sparingly soluble in ethanol(96.0%). Soluble in acetone , in chloroform, in dioxane, in ether and vegetable oils.	符合规定 Conforms	
03	溶液澄清度 Completeness of solution	溶液应澄清, 无不溶物 The solution is clear and free from undissolved solid.	符合规定 Conforms	
04	鉴别 Identification	IR、UV	符合规定 Conforms	
05	熔点 Melting range	≥280℃	280.9℃~283.4℃	
06	比旋度 Specific rotation	+54° ~ +62°	+59.0°	
07	干燥失重 Loss on drying	≤0.5%	0.4%	
08	炽烧残渣 Residue on ignition	≤0.1%	0.08%	
09	杂质总量 Total related substances	≤2.0%	符合规定 Conforms	
10	含量 Assay	97% ~102%	98.1%	
11	残留溶剂 Residual solvents	甲醇≤3000ppm Methanol≤3000ppm	355ppm	
		吡啶≤200ppm Pyridine≤200ppm	未检出 Not Detected	
		乙醇≤5000ppm Ethanol≤5000ppm	未检出 Not Detected	
		二氯甲烷≤600ppm Dichloromethane≤600ppm	未检出 Not Detected	
		丙酮≤5000ppm Acetone≤5000ppm	64ppm	
		苯≤2ppm Benzenes≤2ppm	未检出 Not Detected	
12	颗粒度 Granularity	D[90]<40μm	符合规定 Conforms	
结论 Conclusion		符合以上标准 Meets the above specification		

报告人:
Reporter
日期:
Date

2017.05.10

QC 经理:
QC Manager
日期:
Date

2017.05.10

QA 经理:
QA Manager
日期:
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2017.05.10

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