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分析证明书

CERTIFICATE OF ANALYSIS

Product name: Dydrogesterone 地屈孕酮 152-62-5	
Batch no. 批号: 20221025	Quantity 数量: 30KGS
Manuf. date 生产日期: 2022/10/21	Expiry date 有效期: 2024/10/20

ANALYSIS TEST 检验项目	SPECIFICATIONS 规格	RESULTS 结果
Appearance 外观	White or almost white, crystalline powder 白色或几乎白色结晶性粉末	Conforms 符合规定
Identification(IR) 红外光谱鉴别	The IR spectrum of the sample corresponds to the spectrum of reference standard. 供试品的红外光吸收图谱与对照品一致	Conforms 符合规定
Specific optical rotation 比旋度	-469° ~ -485°	-474°
Related Substances 有关物质	Impurity A NMT 0.3% 杂质 A ≤ 0.3%	< 0.05%
	Impurity B NMT 0.15% 杂质 B ≤ 0.15%	ND
	Impurity C NMT 0.3% 杂质 C ≤ 0.3%	ND
	Unspecified impurities NMT 0.10% 非特定杂质 ≤ 0.10%	ND
	Total impurities NMT 0.5% 总杂质 ≤ 0.5%	< 0.05%
Lose on drying 干燥失重	≤ 0.5%	0.07%
Sulfated ash 硫酸盐灰分	≤ 0.1%	0.01%
Residual Solvents (by GC) 溶剂残留	Ethyl acetate ≤ 0.50%	0.09%
	Dichloromethane ≤ 0.06%	ND
	Methanol ≤ 0.3%	ND
	Acetone ≤ 0.5%	ND
Assay (dried substance) 含量 (按干燥品计)	98.0% ~ 102.0%	100.0%
Storage 储存条件	Preserve in well-closed containers. 密封容器保存	
CONCLUSION: The results conform to Ph.Eur.10.0 结论: 符合 Ph.Eur.10.0		

复核人 Checker:

化验人 Analyst:

