



# Certificate of analysis

Product name: Dienogest

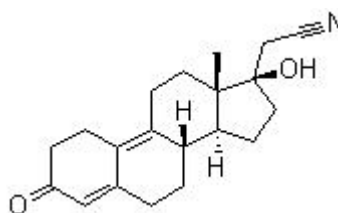
Cas number: **65928-58-7**Molecular Formula: C<sub>20</sub>H<sub>25</sub>NO<sub>2</sub>

Molecular Weight: 311.42

Date of production: Aug. 15, 2020

Batch NO: 20200815

Exp Date: Aug. 14, 2022



Chemical structure:

Items	Specifications		Results
外观 Appearance	白色至类白色或淡黄色结晶性粉末 white, almost white to slightly yellow crystalline powder		淡黄色结晶性粉末 Pale yellow crystalline powder
鉴别 Identification	1	红外鉴别 IR identification	符合规定 Conforms
熔点 Melting point	应为 210°C~218°C From 210°C to 218°C		213°C~214°C
比旋度 Specific rotation	-358.0°~-338.0°		-349.6°
有关物质 Related substances	总杂质 Total impurities ≤0.5%		0.042%
	最大未知单一杂质 Max unknown single impurity ≤0.1%		0.023%
残留溶剂 Residual solvent	四氢呋喃 Tetrahydrofuran ≤0.072%		N.D.
	乙腈 Acetonitrile Ethyl acetate ≤0.041%		N.D.
	二氯甲烷 Dichloromethane ≤0.06%		0.058%
	丙酮 Acetone ≤0.5%		0.016%
干燥失重 Loss on drying	≤0.3%		0.030%
炽灼残渣 Residue on ignition	≤0.1%		0.045%
重金属 Heavy metal	≤10ppm		<10ppm
含量 Assay	98.0%~102.0%		99.98%

**Conclusion: It complies with EP9.0 standard**

Analyst: Zhao

Checker: Liu

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