

CERTIFICATE OF ANALYSIS

Product name	Dienogest		
Batch No.	20191211	Quantity	13kg
Mfg. Date	20191211	Expiry date	20211210
Specification	Enterprise Standard		

Items	Standard	Results
Description	A white or almost white crystalline powder	almost white crystalline powder
Solubility	Practically insoluble in water, slightly soluble in ethanol and acetonitrile, sparingly soluble in N, N-dimethyl formamide and dichloromethane	complies
Identification	HPLC; IR	complies
Melting point	210.0°C ~ 216.0°C	213.0 ~ 214.0°C
Specific rotation	-310.0° ~ -330.0°	-316.0°
Loss on drying	≤ 0.5%	0.02%
Related substances	Impurity A ≤ 0.15%	0.02%
	Single impurity ≤ 0.10%	0.06%
	Total impurity ≤ 0.5%	0.08%
Assay	98.0%-102.0%	99.1%
Residual solvents	Acetone ≤ 5000ppm	961 ppm

Conclusion: The test product complies with the requirements of Enterprise Standard.

Storage condition: room temperature, in a closed container.

Analyst	He qing	Checker	Ye xue ming	Approved by	Ke xian xin
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