



Certificate of analysis

Product name: Gestodene

Cas number: 60282-87-3

Molecular Formula: C₂₁H₂₆O₂

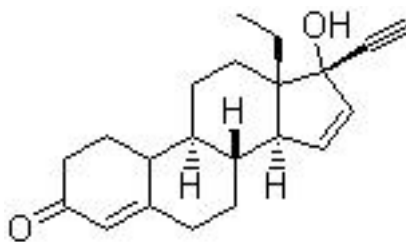
Molecular Weight: 310.43

Date of production: Sep. 26, 2020

Date of Expiry: Sep, 25, 2022

BATCH NO. ; 20200926

Chemical structure:



Items	Specifications	Results
Appearance	White or yellowish crystalline power	Complies
IDENTIFYCATION	The IR spectrum obtained is in concordance with the reference standard.	Complies
	The principal peak in chromatogram obtained with the test solution is similar in retention time and size to the principal peak in chromatogram obtained with reference solution.	Complies
Specific Optical Rotation	-188° ~ -199° (0.01g/ml, methanol)	-192°
Related substances	Impurity A at 254nm: 6-gestodene ≤ 0.31%	0.05%
	Impurity B at 205nm: 5(10)-gestodene ≤ 0.20%	0.05%
	Impurity C at 254nm: 20isopropanol-gestodene ≤ 0.20%	N.D
	Impurity I at 205nm: 5-methoxy-gestodene ≤ 0.15%	N.D
	Impurity L at 205nm: 5(6)-gestodene ≤ 0.15%	N.D
	Individual unspecified impurity ≤ 0.1%	0.07%
	Total impurities at 254nm: ≤ 0.5%	0.18%
Residual solvents	Acetone ≤ 5000ppm	2113ppm
	Ethyl acetate ≤ 5000ppm	957ppm
Loss on drying	≤ 0.5%	0.3%
Assay	97.0%-102.0%	99.8 %

Conclusion: It complies with EP8.0 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F