

SHAANXI FUJIE PHARMACEUTICAL CO., LTD

CETIFICATE OF ANALYSIS

Product Name:	Glycyrrhetic Acid (ENOXOLONE)	Source:	Product Department
Production Batch:	2019010105	Quantity:	120kg
Manufacturing Date:	2019.01.06	Expiry Date:	2021.01.05
Sampling Date:	2019.01.08	Report Date:	2019.01.13
Test Method:	European Pharmacopoeia 9.0		

Analysis	Specification	Results
CHARACTERS		
Appearance	White or almost white crystalline powder	Complies
Solubility	Practically insoluble in water、soluble In ethanol、sparingly soluble in methylene Chloride.It shows polymorphism.	Complies
IDENTIFICATION		
IR or TLC and Coloured reaction	Positive	Complies
Appearance of Solution	The solution is clear and not more intensely coloured than reference solution Y6	Complies
TESTS		
Specific optical rotation:	+1450~+1540	+152.90
Related Substance		
Any impurity	≤ 0.7%	0.2%
Total impurity	≤ 2.0%	1.3%
Heavy metals	≤ 10ppm	Complies
Loss on drying	≤0.5%	0.15%
Sulphated Ash	≤0.2%	Complies
Residual ethanol	≤0.5%	0.1%
Assay (by Potentiometry)	98.0-101.0%(dried substance)	98.6%

Determined: The goods by the European Pharmacopoeia 9.0, the results of compliance.

Inspector: 李可

Re-inspector: 庞产军

Quality Manager: 石向军

Factory : Yuanqu Yi Road, Qinghe Food Industrial Park, Sanyuan County, Shaanxi Province, China

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