



Certificate of analysis

Productname: **Fulvestrant**

Cas number: 129453-61-8

Molecular Formula: C₃₂H₄₇F₅O₃S

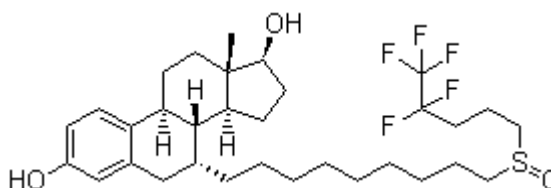
Molecular Weight: 606.77

Date of production: Oct. 24, 2017

Batch NO: 20171024

Exp Date: Oct. 23, 2019

Chemical structure:



Item	Specification	Test Result
Appearance	White Crystalline powder	Conform
Identification	IR HPLC	Conform
Specific Rotation	Between +108° and +115°	+113.0°
Water	Not More Than 0.5%	0.3%
Residue on ignition	Not More Than 0.1%	<0.1%
6-Keto-fulvestrant	Not More Than 0.1%	ND
6,7-Fulvestrant	Not More Than 0.1%	0.06%
Fulvestrant sulfone	Not More Than 0.2%	ND
Fulvestrant extended	Not More Than 0.3%	ND
Fulvestrant sterol dimer	Not More Than 0.8%	ND
Any individual unspecified impurity	Not More Than 0.1%	0.07%
Total impurities	Not More Than 1.0%	0.6%
Fulvestrant A	42% ~ 48%	45%
Fulvestrant B	52% ~ 58%	55%
Assay(HPLC)	97.0% to 102.0%	99.1%

Conclusion: It complies with the USP32 Standard.