

Certificate of Analysis

Product Name: Fulvestrant CAS:129453-61-8

Batch No.: 20240525

Mfg. Date: 2024/05/25

Re-test Date: 2025/05/24

Quantity: 3000 Grams

Invoice Number: F2024224

Tests	Specification	Result
Appearance	White to off-white crystalline powder	Conform
Specific rotation	+108° ~ +115°	+110.8°
Identification	IR absorption; HPLC	Conform
Impurity F (6-keto-fulvestrant)	≤0.1%	N.D.
Impurity C (Fulvestrant extended)	≤0.3%	N.D.
Impurity D (Fulvestrant sterol dimmer)	≤0.8%	N.D.
Impurity B (Fulvestrant sulfone)	≤0.2%	0.05%
Other max. Unknown impurity	≤0.1%	0.03%
Total impurity	≤1.0%	0.10%
Ratio of isomers (A:B)	42~48 : 52~58	46.7:53.3
Residue on ignition	≤0.1%	0.04%
Loss on drying	≤0.5%	0.31%
Assay (on dried basis)	97.0%~102.0%	99.7%
Methanol & Isopropyl acetate	3000ppm	N.D.
Dichloromethane	600ppm	N.D.
Ethyl acetate	5000ppm	2932ppm
Toluene	890ppm	N.D.
Tetrahydrofuran	720ppm	N.D.

Conclusion: The above mentioned items conform to the enterprise standard.

Storage conditions: Preserve in well-closed light-resistant containers store refrigerated at 2° to 8° .

Prepared by:

Reviewed by:

Approved by: