

Compounding
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Certificate of Analysis
Bicalutamide

CAS No.	90357-06-5	Code	BIOJBIC001
Batch No	BKL-260414	Manufacture Date	May.28, 2026
Retest Date	May.27, 2028	Quantity	5.5Kgs

Testing Items		Specifications	Results
Appearance		White to off-white crystalline powder	Complies
Identification	IR	The IR spectrum of the sample corresponds to that of the Reference standard	Complies
	HPLC	The retention time of the major peak in the chromatogram of the assay preparation corresponds to than in the chromatogram of standard preparation, as obtained in the assay	Complies
Water		≤0.2%	0.06%
Residue on ignition		≤0.1%	0.02%
Heavy metals		≤10ppm	Complies
Related substances	Bicalutamide Aminobenzonitrile(RRT0.30)≤0.1%		N/D
	Bicalutamide Related Compound A Isomer A(RRT0.64)≤0.1%		N/D
	Bicalutamide Related Compound A Isomer B(RRT0.67)≤0.1%		N/D
	Desfluoro Bicalutamide(RRT0.83)≤0.2%		N/D
	2-Fluoro Bicalutamide(RRT0.94)≤0.2%		0.021%
	Deoxybicalutamide(RRT1.33)≤0.2%		0.019%
	Bicalutamide Sulfide(RRT1.56)≤0.1%		N/D
	Any unspecified impurity≤0.1%		0.036%
	Total impurities≤0.5%		0.076%
Residual solvents	Tetrahydrofuran≤0.072%		N/D
	Toluene≤0.089%		N/D
	N-hexane≤0.029%		N/D
	Acetone≤0.5%		0.023%
	Ethyl Acetate≤0.5%		N/D
	N, N-Dimethyl Acetamide≤0.109%		N/D
Microbiological purity	TAMC≤1000cfu/g		Complies
	TYMC≤100cfu/g		Complies
	Absence of Escherichia coli in 1g		Absence
Assay	98.0%~10.2%		99.3%
Conclusion	This product conforms to USP standard		

***Storage condition: Store below 25°C, Protect from moisture and light.**