



Compounding
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Certificate of analysis
Bicalutamide

CAS No.	90357-06-5	Code	BIOJBIC001
Batch No	BKL-240101	Manufacture Date	Jan.19, 2024
Retest Date	Jan.18, 2026	Quantity	3.5Kgs

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%	0.09%
Residue on ignition		≤0.1%	0.01%
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%	0.01%
		Deoxybicalutamide(RRT1.33)≤0.2%	N/D
		Bicalutamide Sulfide(RRT1.56)≤0.1%	0.008%
		Any unspecified impurity≤0.1%	0.030%
		Total impurities≤0.5%	0.17%
Residual solvents		Tetrahydrofuran≤0.072%	N/D
		Toluene≤0.089%	N/D
		N-hexane≤0.029%	N/D
		Acetone≤0.5%	0.11%
		Ethyl Acetate≤0.5%	N/D
		N, N-Dimethyl Acetamide≤0.109%	N/D
Microbiological purity		TAMC≤500cfu/g	Complies
		TYMC≤50cfu/g	Complies
		Absence of Escherichia coli in 1g	Absence
Assay		98.0%~10.2%	99.7%
Conclusion		This product conforms to USP standard	

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