

Compounding
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Certificate of Analysis
Bicalutamide

CAS No.	90357-06-5	Code	BIOJBIC001
Batch No	BKL-250506	Manufacture Date	May.06, 2025
Retest Date	May.05, 2027	Quantity	4Kgs

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		$\leq 0.2\%$	0.12%
Residue on ignition		$\leq 0.1\%$	0.02%
Heavy metals		$\leq 10\text{ppm}$	Complies
Related substances	Bicalutamide Aminobenzonitrile(RRT0.30) $\leq 0.1\%$		N/D
	Bicalutamide Related Compound A Isomer A(RRT0.64) $\leq 0.1\%$		N/D
	Bicalutamide Related Compound A Isomer B(RRT0.67) $\leq 0.1\%$		N/D
	Desfluoro Bicalutamide(RRT0.83) $\leq 0.2\%$		0.0050%
	2-Fluoro Bicalutamide(RRT0.94) $\leq 0.2\%$		0.020%
	Deoxybicalutamide(RRT1.33) $\leq 0.2\%$		0.12%
	Bicalutamide Sulfide(RRT1.56) $\leq 0.1\%$		N/D
	Any unspecified impurity $\leq 0.1\%$		0.020%
	Total impurities $\leq 0.5\%$		0.15%
Residual solvents	Tetrahydrofuran $\leq 0.072\%$		N/D
	Toluene $\leq 0.089\%$		N/D
	N-hexane $\leq 0.029\%$		N/D
	Acetone $\leq 0.5\%$		0.32%
	Ethyl Acetate $\leq 0.5\%$		N/D
	N, N-Dimethyl Acetamide $\leq 0.109\%$		N/D
Microbiological purity	TAMC $\leq 1000\text{cfu/g}$		Complies
	TYMC $\leq 100\text{cfu/g}$		Complies
	Absence of Escherichia coli in 1g		Absence
Assay	98.0%~10.2%		99.8%
Conclusion	This product conforms to USP standard		

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