

CERTIFICATE OF ANALYSIS

Product Name:	Flutamide		
Batch No.	F180302	Manufacturing Date	March, 2018
Quantity	500kg	Expiry Date	March, 2021
Analytical Results			
Items	Specifications		Results
Characteristics	Pale yellow crystalline powder		Pale yellow crystalline powder
Identification	A: IR Absorption		Complies
	B: HPLC		Complies
Melting range	110-114°C (does not exceed 2°C)		110.5°C-111°C
Loss on drying	Not more than 0.5%		0.1%
Residue on ignition	Not more than 0.1%		0.06%
Related compounds	4-Nitro-3-trifluoro-methylacetanilide: NMT: 0.2%		0.03%
	4-Nitro-3-trifluoro-methylaniline: NMT: 0.15%		0.01%
	3-trifluoromethylaniline: NMT: 0.2%		0.008%
	4-Nitro-3-trifluoromethylpropionanilide: NMT: 0.3%		0.014%
	3-trifluoromethylisobutyranilide: NMT: 0.2%		Not detected
	o-Flutamide:NMT: 0.2%		0.015%
	Unknown (relative response:1.0): NMT: 0.05%		Not detected
	Total unknown: NMT: 0.1%		Not detected
	Total impurities: NMT: 0.4%		0.22%
Residual solvents	Methanol: NMT: 3000ppm		650ppm
Solubility	Freely soluble in acetone ethyl acetate, soluble in chloroform, other practically insoluble mineral oil. petroleum ether and water		Meets the requirements
Heavy Metals	Not more than 10ppm		Not detected
Assay	98.0-101.0% (calculated on the dried basis)		99.55%
Conclusion	Complies with USP39.		

Inspector: Carlifor Wu

Verifier: Jack He

