

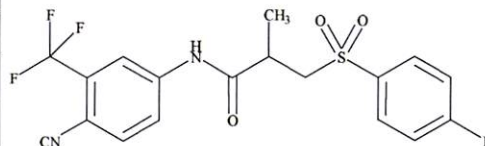
Certificate of Analysis

Certificate No.: **20240517010**



Date: May 17, 2024

Retest date: May 14, 2027

Compound Name: Bicalutamide EP Impurity C (Deshydroxy Bicalutamide)	
Synonyms:	<i>N</i> -(4-cyano-3-(trifluoromethyl)phenyl)-3-(4-fluorophenylsulfonyl)-2-methylpropanamide
TLC Catalogue Number:	B-0216
CAS Number:	906008-94-4
Molecular Weight:	414.37
Molecular Formula:	C ₁₈ H ₁₄ F ₄ N ₂ O ₃ S
Source:	TLC Pharmaceutical Standards
Source Lot No.:	6114-020A3
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO



Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.9%
Impurity (HPLC)	N/A	
Water Content (KF)	N/A	0.1%
Residual Solvents (NMR)	0.1% methanol	
Assay (%)	Not less than 90.0%	99.7%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		05/21/2024
Approved by:	Quality Assurance		05/21/2024

Attachments: HPLC, IR, MS and NMR spectra.