

Certificate of Analysis

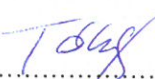
Date: 23 August 2019

Name of the product	Bicalutamide
CAS Name	(2RS) N-{4-Cyano-3-(trifluoromethyl)phenyl}-3-{(4-fluorophenyl)sulfonyl-2-hydroxy-2-methyl-propanamide
CAS No	90357-06-5
Batch No.	04M0181003
Date of Manufacture	July 2018
Date of Analysis	October 2018
Retest date	July 2021

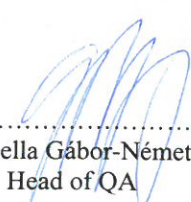
Tests (Methods)	Requirements	Results
Appearance	White or almost white powder	White powder
Identification (IR)	Conforms to reference spectrum	Conforms
Loss on drying	NMT 0.50%	0.23%
Sulphated ash	NMT 0.10%	LT 0.05%
Heavy metals	NMT 10 ppm	LT 10 ppm
Assay (HPLC)	99.0-101.0% (on dried substance)	99.8%
Related substances (HPLC)		
Impurity C	NMT 0.15%	LT 0.05%
Unspecified Impurity, each	NMT 0.10%	LT 0.05%
Total Impurities	NMT 0.50%	LT 0.05%
Additional tests (Methods)		
Identification (HPLC)	Conforms to reference standard	Conforms
Optical rotation	-0.10° to +0.10°	+0.10°
Residue of Catalyst		
Pd	NMT 5 ppm	LT 1.6 ppm
Cu*	NMT 15 ppm	Not tested
Melting range (Ph.Eur. 2.2.14)	190-194 °C	190-193°C
Related substances - BA II Impurity	NMT 10 ppm	LT 5 ppm
Residual solvents (HS-GC)		
Dimethylformamide	NMT 400 ppm	LT 109 ppm
Dichloromethane	NMT 300 ppm	LT 20 ppm
Toluene	NMT 200 ppm	LT 60 ppm
Dimethylacetamide	NMT 400 ppm	LT 97 ppm
Tetrahydrofuran	NMT 72 ppm	LT 26 ppm
Benzene	NMT 2 ppm	LT 0.8 ppm
Acetone	NMT 1000 ppm	LT 190 ppm
n-Heptane	NMT 1000 ppm	LT 402 ppm
Isopropanol	NMT 1000 ppm	LT 286 ppm
Ethyl acetate	NMT 1000 ppm	LT 351 ppm
Particle size distribution		
Below 1 µm	NMT 20%	0%
Below 10 µm	NLT 60%	89%
Below 20 µm	NLT 90%	100%
Microbiology**		
TAMC	NMT 10 ³ CFU/g	Not tested
TYMC	NMT 10 ² CFU/g	Not tested
E. coli	Absent/g	Not tested

* Tested in every 10th batch ** Tested in every 5th batch.

The product meets the requirements.


 Gergely Tóth
 Head of QC




 Gabriella Gábor-Németh
 Head of QA