

09/01/2023

CERTIFICATE OF ANALYSIS
BICALUTAMIDE Ph.Eur.

Format No. : QA/FM-235/01

Batch No. : BL-22003(JM-01)-001	Date of Mfg. : MAR-2022
AR. No. : FG/0167/22	Date of Exp. : FEB-2027
Batch Qty. : 109.700 Kg	Date of Release : 09/04/22

Sr. No.	TESTS	RESULTS	SPECIFICATION
1.	Description	White powder.	White or almost white powder.
2.	Solubility	Complies	Practically insoluble in water, freely soluble in acetone, slightly soluble in anhydrous ethanol and in methylene chloride.
3.	Identification (By IR)	Complies	The Infra Red spectrum of Sample should concordant with similar preparation of that of Bicalutamide WS.
4.	Loss on drying (at 105°C for 4 hours)	0.14 %	Not more than 0.5%
5.	Sulfated ash	0.03 %	Not more than 0.1%
6.	Related substances (By HPLC) Test- A	Not detected	Impurity C : Not more than 0.15%
		Below disregard limit	Unspecified impurities
		Below disregard limit	Impurity A : Not more than 0.10%
		Below disregard limit	Impurity B : Not more than 0.10%
		Not detected	Impurity D : Not more than 0.10%
		Not detected	Impurity E : Not more than 0.10%
		Not detected	Impurity F : Not more than 0.10%
		Below disregard limit	Impurity J : Not more than 0.10%
		Not detected	Impurity M : Not more than 0.10%
		Below disregard limit	Any other impurity : Not more than 0.10%
		Below disregard limit	Total impurities : Not more than 0.5%
	Test -B	Not detected	4-Amino-2- Trifluoromethylbenzonitrile (ATM) : Not more than 10 ppm
		Not detected	4-Amino-3-trifluoromethylbenzonitrile (ATM isomer) : Not more than 10 ppm
		Not detected	2,3-Epoxy-2-methyl-N-[4-cyano-3- (trifluoromethyl) phenyl] propanamide(BA-II) : Not more than 10 ppm
7.	Assay (By HPLC)	99.50 %	Not less than 98.5% w/w and Not more than 101.0% w/w on dried basis.

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BICALUTAMIDE Ph.Eur.

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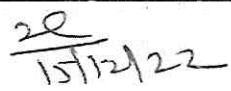
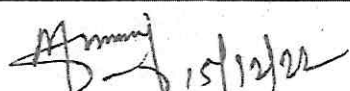
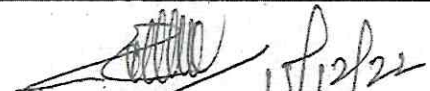
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8.	Residual Solvents (By HSGC)	8 ppm	Acetone : Not more than 5000 ppm
		107 ppm	Ethyl formate : Not more than 5000 ppm
		Not detected	Dichloromethane : Not more than 600 ppm
		Not detected	Ethyl Acetate : Not more than 5000 ppm
		Not detected	Toluene : Not more than 890 ppm
9.	Polymorphism (By XRD)	Complies	The XRD peak at 2 Theta value at 12.3 ($\pm$ 0.2) should be present. Pattern matches with that of standard XRD spectrum of polymorph form I.

Additional Test

1.	Particle Size	5.39 μ m	D(v,0.90):Not more than 10 μ m
2.	Microbial limits 1.Total Viable Count (Microbial Enumeration test) 1.1)Total Aerobic Microbial count (TAMC) 1.2)Total combined yeast and mould count(TYMC) 2. Test for specified Microorganism 2.1) Bile tolerant gram negative bacteria 2.1.1) Test for Absence 2.1.2) Quantitative test 2.2) Escherichia coli 2.3)Salmonella 2.4) Pseudomonas aeruginosa 2.5) Staphylococcus aureus 2.6) Candida albicans	< 10 CFU / g < 10 CFU / g Absent < 10 CFU / g Absent Absent Absent Absent Absent Absent	< 1000 CFU / g < 100 CFU / g Absent / g < 10 CFU / g Absent / g Absent / 10 g Absent / g Absent / g Absent / g

Remark: The material Complies as per Ph.Eur. and above specification.

Prepared By	Checked By	Approved By
		
Executive Designee Quality Assurance	Manager Designee Quality Assurance	Head Quality Assurance/ Quality Control Designee

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