METAPHARMACEUTICAL

N DE LOTE: 0010525

02/05/2025

KEKULE PHARMA LIMITED

Inspired by Life. Driven by Science.

CERTIFICATE OF ANALYSIS

Product	:	BICALUTAMIDE Ph.Eur			
Batch Number	:	BICE 0020225	Quantity	:	2.34 kg
Mfg. Date	:	Feb' 2025	Expiry date	:	Jan' 2030
Analysis completed on	:	19.02.2025	AR Number	:	FP/BICE/002/25

S.No	Test	Specification	Result
1.0	Appearance	White or almost white powder	White powder
2.0	Solubility	Practically insoluble in water, freely soluble in acetone,slightly soluble in anhydrous ethanol and in methylene chloride	Complies
3.0	Identification by		
	IR	The absorption maxima in the spectrum obtained with the sample shall correspond in position and relative intensity to those in the spectrum obtained with that of standard.	Complies
	XRD*	XRD should be concordant with Form-1 WS XRD	Complies
4.0	Loss on drying	Not more than 0.5% w/w	0.13% w/w
5.0	Sulphated Ash	Not more than 0.1%w/w	0.04% w/w
6.0	Related substances by HPLC		
	*a) 4-cyano-3- (trifluoromethyl) benzamido-2-methyl-1, 2-epoxide (Impurity-I)	Not more than 0.001%	Not detected
	*b) 4-cyano-N-methocryoyl-3-trifluoromethylaniline (BICE-0)	Not more than 0.001%	Not detected
	c) Impurity C	Not more than 0.15%	Not detected
	d) Unspecified impurities	Not more than 0.10%	0.02%
	e) Total impurities	Not more than 0.50%	0.04%
7.0	Assay by HPLC (on dried substance)	97.5% to 102.0% w/w.	99.2% w/w
*8.0	Residual solvents by GC		
	a) Acetone	Not more than 500 ppm	346 ppm
	b) Methylene chloride	Not more than 200 ppm	BQL
	c) Di isopropyl ether	Not more than 80 ppm	3 ppm
	d) Ethyl acetate	Not more than 500 ppm	55 ppm
	e) Tetra hydro furan	Not more than 50 ppm	Not detected
	f) Toluene	Not more than 50 ppm	Not detected
	g) Benzene	Not more than 2 ppm	Not detected

Prepared by	Approved by	Released by
28/3/25	28/03/25	31/03/25
Sign /Date	Sign /Date	Sign /Date
Quality Control	Quality control	Quality Assurance

Regd. Office & Corporate Office : H.No. 8-3-680, Opp Vishal Towers, LIC Colony, Yellareddy Guda, Hyderabad - 500 073, T.S., India.
Ph: +91-402373-3225 / 2373-6150, Fax : +91-40-2374-4822
Mfg. Site : Sy. NO. 180/1 to 15, MIA, Khazipally (V), Jinnaram (M), Sangareddy (Dist) - 502 319, T.S., India. Ph: +91-8458-277230/277070, Email : contact@kekulepharma.cor
www.kekulepharma.com

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S.No	Test	Specification	Result
*9.0	Microbial Limits		
	a) Total Viable Aerobic Count	Not more than 1000 cfu/gm	20 CFU/gm
	b) Total Fungal Count	Not more than 100 cfu/gm	Nil
*10.0	Particle size		
	a) D(v,0.10)	Not less than 0.1 µm	0.60 µm
	b) D(v,0.50)	Between 1 to 5 µm	1.90 µm
	c) D(v,0.90)	Not more than 10 µm	4.55 µm

* - In-House Specification

Rest of test's as per Ph.Eur

Abbreviations

Impurity-C : (2RS)-N-[4-CYANO-3-(trifluoromethyl) phenyl]-3-[(4-fluorophenyl) sulfonyl]-2-methylpropanamide

Mfg: Manufacturing, AR: Analytical report, ppm: parts per million. BQL: Below quantification Limit, BDL: Below Detection Limit

Result: The Product conforms to the CEP grade.

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