

Hetero Labs Limited (Unit-I) Factory : Survey No.10, I.D.A., Gaddapotharam, Jinnaram Mandal, Sangareddy District-502319, Telangana, INDIA. Phone : 91-8458-277106, Fax : 91-8458-277135		
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CERTIFICATE OF ANALYSIS

Product: BICALUTAMIDE (Form-H1)					
Batch No.	BT24010009	Reference STP No.	BT-010-05	Analytical Report No.	HL02FP24000244
Reference	Ph.Eur	Date of Manufacture	28-01-2024	Status	Initial Certification
Batch Quantity	102.100 Kg	Date of Analysis	27-02-2024	Retest Date	27-01-2029

S. No.	TEST	RESULT	SPECIFICATION
1	Description (Ref.: Visual Inspection)	A white powder.	White or almost white powder.
2	Solubility (Ref.: Visual Inspection Ph.Eur 1.4)	Complies.	Practically insoluble in water, freely soluble in acetone, slightly soluble in anhydrous ethanol and methylene chloride.
3	Identification by		
3.1	IR absorption (Ref.: Ph.Eur 2.2.24)	Matches with Working standard.	The Infrared absorption spectrum of the finely ground sample in KBr dispersion compressed into a disc should exhibit maxima only at the same wavelengths as that of a similar preparation of Bicalutamide (Form-H1) Working Standard.
3.2	HPLC (Ref.: Ph.Eur 2.2.29 In-House)	Matches with working standard.	The retention time of the major peak in the chromatogram of the test solution should corresponds to that in the chromatogram of the Reference solution, as obtained in the assay by HPLC test.
4	Loss on Drying (Ref.: Ph.Eur 2.2.32)	0.23 %w/w	Not more than 0.50% w/w.
5	Sulphated ash (Ref.: Ph.Eur 2.4.14)	0.04 %w/w	Not more than 0.10% w/w.
6	**Optical rotation (c=1%w/v in methanol) (Ref.: Ph.Eur.2.2.7)	-0.002 °	Between -0.005° and +0.005°
7	Related Substances by HPLC		
7.1	Test -A (Ref:Ph.Eur 2.2.29 In-House)		
7.1.1	(2RS)-N-[4-cyano-3-(trifluoromethyl)phenyl]-3-[(4-fluorophenyl)sulfinyl]-2-methyl-propanamide :Impurity C (BTRC07)	Not Detected	Not more than 0.10%
7.1.2	(2RS)-N-[4-cyano-3-(trifluoromethyl)phenyl]-3-[(RS)-(4-fluorophenyl)sulfinyl]-2-hydroxy-2-methylpropanamide. & (2SR)-N-[4-cyano-3-(trifluoromethyl)phenyl]-3-[(RS)-(4-fluorophenyl)sulfinyl]-2-hydroxy-2-methylpropanamide.	0.02 %	Not more than 0.10%

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By M.Samba Siva Reddy 27-02-2024 12:22	Reviewed By P.Saiam 27-02-2024 12:35	Approved By BHUMIREDDY.OBULA REDDY 27-02-2024 13:17
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	nyl)sulfinyl]-2-hydroxy-2-methylpropanamide. Impurity E and F		
7.1.3	Unspecified impurity	0.01 %	Not more than 0.05%
7.1.4	Total impurities	0.03 %	Not more than 0.30%
7.2	Test-B (Ref: Ph.Eur 2.2.29 In-House)		
7.2.1	2,3-Epoxy-2-methyl-N-[4-cyano-3-(trifluoromethyl)phenyl]propanamide.# BTRC01	Not Detected	Not more than 10 ppm (LOQ:3 ppm)
8	Assay by HPLC (On dried basis) (Ref:Ph.Eur 2.2.29)	99.5 % w/w	Not less than 98.0% and Not more than 101.0% w/w.
9	*Residual solvents by GC (Ref.:Ph.Eur 2.2.28, 5.4 (In-House))		
9.1	Acetone	1008 ppm	Not more than 4000 ppm (LOQ:6 ppm)
9.2	Dichloromethane	Not Detected	Not more than 200 ppm (LOQ:24 ppm)
9.3	Diisopropyl ether	6 ppm	Not more than 200 ppm (LOQ:6 ppm)
9.4	Ethyl acetate	Not Detected	Not more than 200 ppm (LOQ:24 ppm)

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