



# HETERO LABS LIMITED (UNIT-I)

(Formulations Division)

## CERTIFICATE OF ANALYSIS

<b>Product Name: Califox 50 (Bicalutamide Tablets IP 50mg)</b>			
<b>Product Code</b>	4035457	<b>A.R. No.</b>	H5FP25000480
<b>Specification ID</b>	FPS/B-3006186-1-03	<b>Batch No.</b>	AFX250101
<b>Mfg. Date</b>	01/2025	<b>Batch Size</b>	50000 Tablets
<b>Exp. Date</b>	12/2026	<b>Date Of Release</b>	03-02-2025

S. No.	TEST	RESULT	SPECIFICATION
1	Description	White coloured, capsule shaped, film coated tablets with break line on one side.	White coloured, capsule shaped, film coated tablets with break line on one side.
2	Identification (By HPLC)	The retention time of the major peak in the chromatogram of the sample solution corresponds to that in the chromatogram of the standard solution, as obtained in the assay.	The retention time of the major peak in the chromatogram of the sample solution should correspond to that in the chromatogram of the standard solution, as obtained in the assay.
3	Average weight	286.04 mg	285.60mg $\pm$ 3% (277.03mg to 294.17mg)
4	Uniformity of weight	Highest : 1.86 % Lowest:-1.29 %	$\pm$ 5.0% of Average Weight
5	Water content (By KF)	4.48 % w/w	Not more than 6.0% w/w.
6	Uniformity of dosage units (Content uniformity, By HPLC) Acceptance value (L1)	3.3	Not more than 15.0
7	Dissolution (By UV)	Tablet 1- : 101.6 % Tablet 2- : 100.1 % Tablet 3- : 99.9 % Tablet 4- : 98.2 % Tablet 5- : 100.8 % Tablet 6- : 100.4 % Average::100.2 %	Not less than 70% (Q) of labeled amount of Bicalutamide should dissolve in 60 minutes.
8	Related Substances (By HPLC)		
8.1	Maximum single Impurity	0.03 %	Not more than 1.0%
8.2	Total Impurities	0.08 %	Not more than 2.0%
9	Assay (By HPLC) Each film coated tablet contains:	102.3 %	Not less than 95.0 and Not more than 105.0

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Dharmendra.Kumar	Approved By	Naveen Kumar.Pundir
Date	06-02-2025 16:17	Date	06-02-2025 16:18
Printed by: Naveen Kumar.Pundir		Printed on: 06-02-2025 16:18	
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**Approved By**  
Name: Naveen Kumar  
Designation: Manager  
Qualification: M. Sc.  
Registration Number: M-0013423  
University: Chaudhary Charan Singh University, Meerut.



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	<b>Bicalutamide IP (C<sub>18</sub>H<sub>14</sub>F<sub>4</sub>N<sub>2</sub>O<sub>4</sub>S) (%)</b>		
	<b>Labeled amount</b>		
10	<b>Residual solvents (By GC)</b>		
10.1	<b>Isopropyl Alcohol</b>	95 ppm	Not more than 5000 ppm
10.2	<b>Methylene chloride</b>	Not Detected	Not more than 600 ppm

Remarks: APPROVED (Sample Conforms to above Specification)

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