



# HETERO LABS LIMITED (UNIT-I)

## (Formulations Division)

### CERTIFICATE OF ANALYSIS

<b>Product Name: BIRAFOX 250 (Abiraterone Acetate Tablets IP 250mg)</b>			
<b>Product Code</b>	4033378	<b>A.R. No.</b>	H5FP25000704
<b>Specification ID</b>	FPS/B-3011458-1-01	<b>Batch No.</b>	AMA250207
<b>Mfg. Date</b>	02/2025	<b>Batch Size</b>	20000 Tablets
<b>Exp. Date</b>	01/2027	<b>Date Of Release</b>	12-02-2025

S. No.	TEST	RESULT	SPECIFICATION
1	Description	White colored, oval shaped, biconvex, uncoated tablets with breakline on one side and plain on another side.	White to off white colored, oval shaped, biconvex, uncoated tablets with breakline on one side and plain on another 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	610.86 mg	610.00mg $\pm$ 3% (591.70mg to 628.30mg)
4	Uniformity of weight	Highest : 0.72 % Lowest:-0.73 %	$\pm$ 5% of average weight
5	Water content (By KF)	3.22 % w/w	Not more than 7.0% w/w
6	Uniformity of dosage units (By Weight variation) Acceptance Value (L1)	1.3	Not more than 15.0
7	Dissolution (By HPLC)	Tablet - 1 : 100.8 % Tablet - 2 : 96.5 % Tablet - 3 : 100.0 % Tablet - 4 : 100.2 % Tablet - 5 : 100.6 % Tablet - 6 : 100.3 % Average::99.7 %	Not less than 75% (Q) of the labeled amount of Abiraterone Acetate is dissolved in 60 minutes.
8	Related substances (By HPLC)		
8.1	Maximum single impurity	Not Detected	Not more than 0.5% w/w
8.2	Total impurities	Not Detected	Not more than 1.0% w/w
9	Assay (By HPLC) Each uncoated tablet contains:	98.6 %	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	13-02-2025 15:26	Date	13-02-2025 15:28
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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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Abiraterone Acetate IP (C <sub>26</sub> H <sub>33</sub> NO <sub>2</sub> ) (%) Labeled amount		

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