HETERO LABS LIMITED (UNIT-I)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: BIRAFOX 250 (Abiraterone Acetate Tablets IP 250mg)			
Product Code	4033378	**A.R. No.**	H5FP26004753
Specification ID	FPS/B-3011458-1-01	**Batch No.**	AMA260902
Mfg. Date	09/2026	**Batch Size**	20000 Tablets
Exp. Date	08/2028	**Date Of Release**	17-09-2026

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**	612.35 mg	610.00mg ± 3% (591.70mg to 628.30mg)
4	**Uniformity of weight**	Highest : 0.57 % Lowest::-0.59 %	± 5% of average weight
5	**Water content (By KF)**	2.80 % w/w	Not more than 7.0% w/w
6	**Uniformity of dosage units (By Weight variation) Acceptance Value (L1)**	1.0	Not more than 15.0
7	**Dissolution (By HPLC)**	Tablet - 1 : 101.7 % Tablet - 2 : 101.0 % Tablet - 3 : 100.2 % Tablet - 4 : 101.3 % Tablet - 5 : 101.3 % Tablet - 6 : 101.2 % Average::101.1 %	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:**	100.7 %	Not less than 95.0 and Not more than 105.0

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	MANVVAR.HASAN	Approved By	Naveen Kumar.Pundir
Date	18-09-2026 12:10	Date	18-09-2026 12:11
Printed by: Naveen Kumar.Pundir		**Printed on: 18-09-2026 12:12**	
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CNo: C170005042			

Approved By
Name: Naveen Kumar
Designation: Sr. Manager
Qualification: M. Sc.
Registration Number: M-0013423
University: Chaudhary Charan Singh University, Meerut

Office : 7-2-A/2, Hetero Corporate, Industrial Estate, Sanath Nagar, Hyderabad-18, INDIA. Tel : 040-23704923/24/25, Fax : 040-23704926
Factory : Village : Kalyanpur, Chakkan Road, BADDI, Tehsil : Baddi, Distt. Solan, H.P. - 173 205 INDIA.

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	Abiraterone Acetate IP (C26H33NO2) (%) Labeled amount		

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