HETERO LABS LIMITED (UNIT-I)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: Birafox 500 (Abiraterone Acetate Tablets IP 500mg)			
Product Code	4037760	**A.R. No.**	H5FP26004774
Specification ID	FPS/B-3011459-1-01	**Batch No.**	AMB260901
Mfg. Date	09/2026	**Batch Size**	14000 Tablets
Exp. Date	08/2028	**Date Of Release**	17-09-2026

S. No.	TEST	RESULT	SPECIFICATION
1	**Description**	White coloured, capsule shaped, biconvex, film coated tablets plain on both sides.	White coloured, capsule shaped, biconvex, film coated tablets plain on both sides.
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**	1147.01 mg	1145.36mg ± 3% (1110.999mg to 1179.721mg)
4	**Uniformity of weight**	Highest : 1.19 % Lowest::-1.39 %	± 5% of average weight
5	**Water content (By KF)**	2.77 % w/w	Not more than 7.0% w/w
6	**Uniformity of dosage units (By Weight variation) Acceptance Value (L1)**	1.6	Not more than 15.0
7	**Dissolution (By HPLC)**	Tablet - 1 : 91.7 % Tablet - 2 : 95.9 % Tablet - 3 : 91.8 % Tablet - 4 : 95.7 % Tablet - 5 : 90.9 % Tablet - 6 : 91.5 % Average::92.9 %	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 film**	100.4 %	Not less than 95.0 and Not

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Dharmendra.Kumar	Approved By	Naveen Kumar.Pundir
Date	30-09-2026 15:50	Date	30-09-2026 15:52
Printed by: Naveen Kumar.Pundir		**Printed on: 30-09-2026 15:52**	
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CNo: C170005327

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

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	coated tablet contains: Abiraterone Acetate IP ($C_{26}H_{33}NO_2$) (%) Labeled amount		more than 105.0

Remarks: APPROVED (Sample Conforms to above Specification)			
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Name: Naveen Kumar
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Factory : Village : Kalyanpur, Chakkan Road, BADDI, Tehsil : Baddi, Distt. Solan, H.P. - 173 205 INDIA.