



**CERTIFICATE OF ANALYSIS ( FINISHED PRODUCT )**

Name of product(Generic)	ABIRATERONE ACETATE TABLETS IP 500 mg		
Name of product(Brand)	BIRAFOX 500		
Product Code	ALT/059A	A .R No.	AL/FG/T/25/372
Mfg. Date	NOV.2025	Generic Batch No.	ABTK25B10
Exp.Date	OCT.2027	Generic Batch Size	30200 Tablets
Specification No.	ALT/SP059A/00	Brand Batch No.	ABTK25B10-A
STP No.	ALT/ST059A/00	Dispatch Qty.	12000 Tablets
Date of sampling	24/11/2025	Date of Release	01/12/2025
Reference	IP&IHS	Page No.	Page 1 of 2

Sr. No.	Test	Specification	Results	Ref.
1.	Description	White to off white coloured oval shape uncoated tablets plain on both side.	Off white coloured oval shape uncoated tablets plain on both side.	IHS
2.	Identification (By HPLC)	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponded to the peak in the chromatogram obtained with the reference solution.	IP
3.	Avg.wt	750 mg ± 5%	749.95 mg	IHS
4.	Length	14.50mm ± 0.20mm	14.58 mm	IHS
5.	Width	11.5 mm ± 0.20 mm	11.56 mm	IHS
6.	Thickness	7.3mm ± 0.20mm	7.34 mm	IHS
7.	Hardness	NLT 4.0 kg/cm <sup>2</sup>	Min. 5.21 kg/cm <sup>2</sup> Max.5.36 kg/cm <sup>2</sup>	IHS
8.	Friability	NMT 1.0%	0.27 %	IHS
9.	Disintegration Time	NMT 15 minutes	05 minutes 48 seconds	IHS
10.	Uniformity of dosage units (By weight variation)	L1- Maximum allowed acceptance value L1=15.0 L2- Maximum allowed range for deviation of each dosage unit tested from the calculated value of M L2= 25.0	1.18	IHS
11.	Dissolution (By HPLC)	NLT 75% (Q) in 60 min	95.79 % to 98.53 %	IP

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Ayush	Tejashree	Atul Sanswat
DESIGNATION	offices	QC Engineer	Asst. Manager
SIGN			
DATE	01/12/2025	01/12/2025	01/12/2025



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12.	Assay (By HPLC) Each uncoated tablet contains Abiraterone Acetate IP 500 mg	NLT 450.0 mg (90.0%) to NMT 550.0 mg (110.0%)	493.70 mg (98.74 %)	IP
13.	Related substances (By HPLC) Any single max. impurity Total impurities	NMT 0.5% NMT 1.0%	0.128 % 0.398 %	IP
14.	Microbial Limits Test A. Total aerobic microbial count B.Total combined yeast and mould count C. Pathogens E. coli Salmonella P. aeruginosa S. aureus	NMT 100 cfu/gm NMT 10 cfu/gm Should be absent/gm Should be absent/10gm Should be absent/gm Should be absent/gm	30 cfu/gm LT 10 cfu/gm Absent/gm Absent/10gm Absent/gm Absent/gm	IHS

Remark: In the opinion of the undersigned the sample Complies/Does not comply with IP/BP/USP/In House specification

Detail of Examiner(s)/Approver:

Name: Atul Sarswat  
 Qualification: M. Tech (Biotechnology)  
 Reg. No./Enrollment No.: A0510709051  
 University Name: Amity University  
 Place: Noida (U.P)

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Aukit	Lakshmi Kumar	Atul Sarswat
DESIGNATION	Officer	QC Executive	Asst Manager
SIGN			
DATE	01/12/2025	01/12/2025	01/12/2025