



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.	H5FP24002459
Specification ID	FPS/B-3011458-1-01	Batch No.	AMA240601
Mfg. Date	06/2024	Batch Size	20000 Tablets
Exp. Date	05/2026	Date Of Release	20-06-2024

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	612.18 mg	610.00mg \pm 3% (591.70mg to 628.30mg)
4	Uniformity of weight	Highest : 2.25 % Lowest:-1.79 %	\pm 5% of average weight
5	Water content (By KF)	3.26 % w/w	Not more than 7.0% w/w
6	Uniformity of dosage units (By Weight variation) Acceptance Value (L1)	3.8	Not more than 15.0
7	Dissolution (By HPLC)	Tablet - 1 : 96.3 % Tablet - 2 : 98.4 % Tablet - 3 : 96.1 % Tablet - 4 : 97.0 % Tablet - 5 : 93.5 % Tablet - 6 : 96.6 % Average::96.3 %	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	102.3 %	Not less than 95.0 and Not

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	MAHENDRA SINGH.BHATI	Approved By	Naveen Kumar.Pundir
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uncoated tablet contains: Abiraterone Acetate IP (C₂₆H₃₃NO₂) (%) Labeled amount		more than 105.0
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