



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. | H5FP25000703 |
| Specification ID | FPS/B-3011458-1-01 | Batch No. | AMA250206 |
| Mfg. Date | 02/2025 | Batch Size | 20000 Tablets |
| Exp. Date | 01/2027 | Date Of Release | 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 | 611.48 mg | 610.00mg \pm 3% (591.70mg to 628.30mg) |
| 4 | Uniformity of weight | Highest : 0.77 % Lowest:-0.64 % | \pm 5% of average weight |
| 5 | Water content (By KF) | 3.18 % w/w | Not more than 7.0% w/w |
| 6 | Uniformity of dosage units (By Weight variation) Acceptance Value (L1) | 0.8 | Not more than 15.0 |
| 7 | Dissolution (By HPLC) | Tablet - 1 : 97.7 % Tablet - 2 : 98.2 % Tablet - 3 : 98.4 % Tablet - 4 : 98.4 % Tablet - 5 : 99.1 % Tablet - 6 : 98.1 % Average::98.3 % | 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 uncoated tablet contains: | 99.3 % | 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 | 12-02-2025 17:55 | Date | 12-02-2025 17:57 |
| Printed by: Naveen Kumar,Pundir | | Printed on: 12-02-2025 17:58 | |
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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 ₂₆ H ₃₃ NO ₂) (%) Labeled amount | | |
|--|--|--|
| | | |

Remarks: APPROVED (Sample Conforms to above Specification)

| | | | |
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| Checked By | Dharmendra.Kumar | Approved By | Naveen Kumar.Pundir |
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