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# VALIDATED AUC METHOD FOR THE SPECTROPHOTOMETRIC ESTIMATION ABIRATERONE ACETATE IN BULK AND TABLET DOSAGE FORM

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## ABSTRACT

A new simple Area under curve spectroscopic method was developed and validated for the estimation of Abiraterone acetate in bulk and pharmaceutical dosage forms and Area under curve was measured at 248-258nm in Methanol. The linearity was found to be in the concentration range of 2-10 µg/ml and the correlation coefficient was found to be 0.9998 and it has showed good linearity, reproducibility, precision in this concentration range. The regression equation was found to be Y=0.0282X+0.0019. The % recovery values were found to be within the 99-100% and showed that the method was accurate. The LOD and LOQ were found to be 0.1278 and 0.3835 µg/ml respectively. The % RSD values were less than 2. The present method is accomplishing the validation parameters according to ICH guidelines. The developed method was successfully applied for the quantitative estimation of Abiraterone Acetate in bulk and pharmaceutical dosage forms.

**KEYWORDS:** Abiraterone acetate, Area under curve, Spectroscopy, Methanol, Linearity, Ruggedness, Precision, Accuracy.

## INTRODUCTION

Abiraterone Acetate is an orally active acetate ester form of the steroidal compound with anti-androgen activity. Abiraterone inhibits the enzymatic activity of steroid 17alpha-monooxygenase, a member of the Cytochrome P450 family that catalyzes the 17alpha-hydroxylation of steroid intermediates involved in testosterone synthesis. Administration of this agent may suppress testosterone production by both the testes and the adrenals to castrate-range levels.[1] It has been used to treat prostate cancer. The chemical name of Abiraterone acetate is (3ß)-17-(3-Pyridinyl) androsta-5,16-diene-3-yl acetate. It has a molecular formula $C_{23}H_{33}NO_2$ and molecular weight of 391.5 gm/mol. Abiraterone acetate is freely soluble in Acetonitrile and methanol.[1-2]

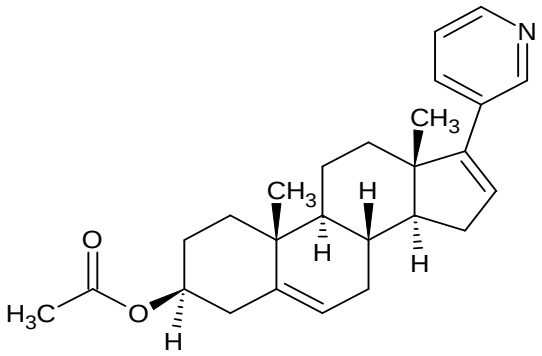


**Fig 1: Chemical structure of Abiraterone acetate.**

Literature survey revealed that there were some analytical methods have been reported for the estimation of Abiraterone in pure drug and pharmaceutical dosage forms by using UV spectrophotometric,[3-5] HPLC[6-13] so far.

The aim of present work is to develop and validate a novel, simple, rapid, precise, and specific Area under curve UV spectrophotometric method for the estimation of Abiraterone acetate in bulk and tablet dosage form.

## MATERIALS AND METHOD

### Instrument

UV-Visible double beam spectrophotometer, SHIMADZU (model UV-1800) with UV probe software. All weights were taken on analytical balance.

### Chemicals

- Abiraterone Acetate pure form was obtained as a gifted sample from MSN Laboratories private limited at Nandigama. and its pharmaceutical dosage form 500mg. Manufactured by BDR Pharmaceuticals Int'l pvt ltd, Vadodara-Gujarat. Batch No: HARBN3119 procure from local pharmacy Mandya.
- Methanol available in the laboratory of Bharathi College of Pharmacy, Bharathinagara.

**Solvent**
**Methanol**
**Selection of Analytical Wavelength**
Appropriate dilutions were prepared for Abiratirone acetate from the standard stock solution and the solution was scanned in the wavelength range of 200-400nm. The absorption spectra thus obtained were derivatized from Area under curve method which is shown in Fig2.

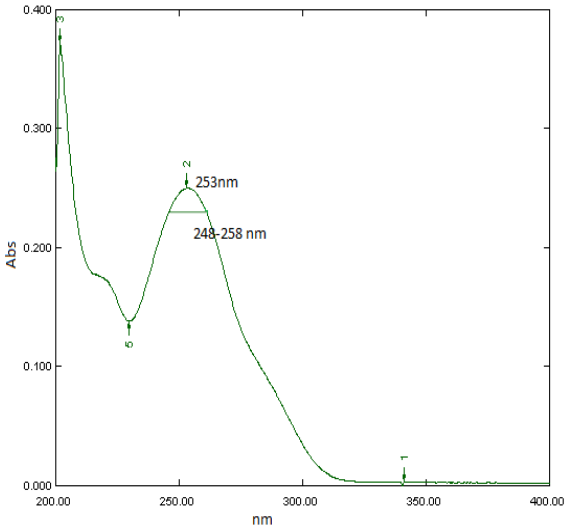


**Fig 2: Typical Zero order spectra of Abiraterone acetate showing Area under curve (AUC) from 248nm to 258nm.**

**Preparation of standard stock solution**
10 mg of Abiraterone acetate was accurately weighed and transferred into 10ml volumetric flask and diluted with Methanol up to the mark. From this solution pipette out 1ml into 10ml volumetric flask and dilute with Methanol up to the mark, from this solution pipette out 0.2, 0.4, 0.6, 0.8 and 1.0ml into10ml individual volumetric flask and add methanol up to the mark, this gives 2, 4, 6, 8 and 10 µg/ml concentrations.

**Preparation of sample solution**
20 tablets of Abiraterone acetate marketed formulations were weighed and powdered. The tablet powder is equivalent to 100mg of Abiraterone acetate was transferred into 100ml volumetric flask then it was diluted with Methanol and made up to mark. From this solution pipette out 10ml into a 100ml volumetric flask and make up to the mark with methanol.

**Method and Validation**
The method was validated according to the various parameters of ICH guidelines.

## RESULTS AND DISCUSSION
**Method:** Area under curve spectroscopy.

**Linearity**
The linearity of an analytical method is its capacity to show the test results that are directly proportional to the concentration of the analyte bin the sample within the range. The linearity was established in the concentration range of 2-10 µg/ml was measured 248-258nm and absorbance values are shown in table-1. The calibration curve was prepared by plotting graph against the concentration and absorbance and the graph shown in Fig-3. Statistical parameters like slope, intercept, regression equation, correlation coefficient and Sandell's sensitivity were determined (Table-2).

**Table 1: Results of calibration curve at 248-258nm by Area under curve.**

| SL NO | Concentration in µg/ml | Absorbance ±Standard deviation** |
|---|---|---|
| 1 | 0 | 0 |
| 2 | 2 | 0.059±0.00238 |
| 3 | 4 | 0.117±0.00445 |
| 4 | 6 | 0.171±0.004367 |
| 5 | 8 | 0.228±0.008287 |
| 6 | 10 | 0.283±0.00863 |

**Average of six determination

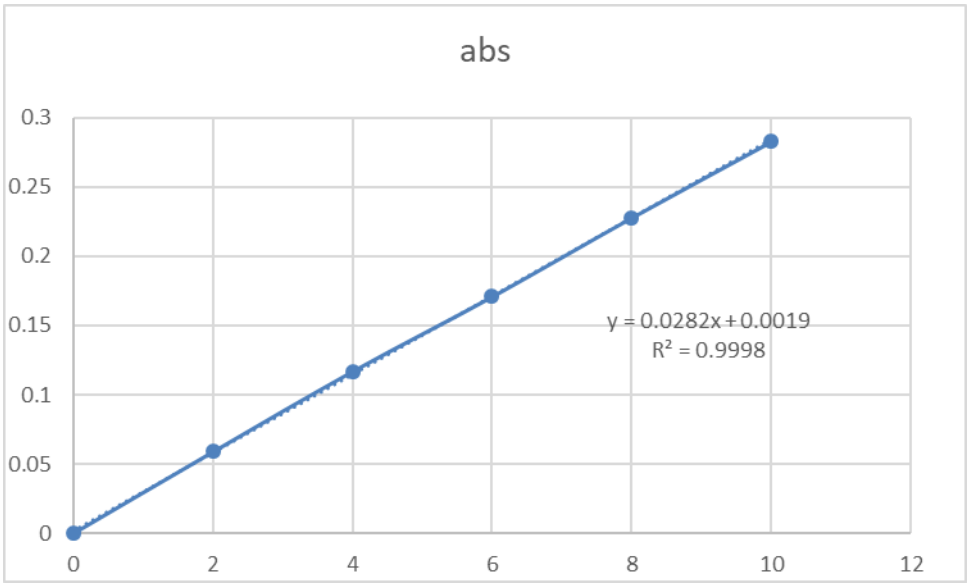


**Fig 3: Calibration curve of Abiraterone acetate by Area under curve method.**

**Table 2: Regression parameters for Abiraterone acetate by Area under curve method.**

| Regression Parameters | Abiraterone acetate |
|---|---|
| Range | 2-10 |
| AUC wave lengths | 248-258 |
| Regression Equation | Y=0.0282x+0.0019 |
| Slope(b) | 0.0282 |
| Intercept(a) | 0.0019 |
| Correlation Coefficient$(R)^2$ | 0.9998 |
| Sandell's Sensitivity | 0.0350877193 |
| Limit of detection(µg/ml) | 0.1278 |
| Limit of quantitation(µg/ml) | 0.3835 |

**Precision**

The precision of an analytical method expresses the closeness of a series of individual analyte measurements obtained from multiple sampling of the sample.

Precision was determined by intraday and interday study. Intraday precision was determined by analyzing the 2,4,6,8 and 10 µg/ml for three times in a same day. Interday precision was determined by analyzing the same concentration daily for three different ways. Precision results are shown in table 3.

**Table 3: Determination of precision results for Abiraterone acetate at 248-258nm by Area under curve.**

| Concentration (µg/ml) | Intra-day Area under curve ±SD** | %RSD | Inter-day Area under curve ±SD** | %RSD |
|---|---|---|---|---|
| 2 | 0.063±0.000816 | 1.2952 | 0.057±0.000816 | 1.4315 |
| 4 | 0.121±0.001414 | 1.1685 | 0.114±0.001247 | 1.0907 |
| 6 | 0.182±0.00216 | 1.1868 | 0.167±0.002025 | 1.5687 |
| 8 | 0.239±0.000170 | 0.70933 | 0.222±0.002055 | 0.944 |
| 10 | 0.293±0.002794 | 0.8503 | 0.274±0.002944 | 1.0744 |

**Average of three determinations
**percentage relative standard deviation.

**Accuracy**

The accuracy of an analytical method describes that closeness of test results obtained by that method to the true value. To assess the accuracy of the developed method, recovery studies were carried out at three different levels as 80%, 100% and 120%. In which the

formulation concentration was kept constant and varied pure drug concentration. Accuracy results were shown in table.4.

**Table 4: Determination of Accuracy results for Abiraterone acetate at 248-258nm by Area under curve.**

| Spiked Levels | Amount of Sample (µg/ml) | Amount of Standard (µg/ml) | Amount Recovered | %Recovery ±Standard Deviation* | %RSD* |
|---|---|---|---|---|---|
| 80 | 6 | 4.8 | 10.7 | 99.77 ±0.8523 | 0.8542 |
| 100 | 6 | 6 | 12.04 | 100.4 ±0.9263 | 0.9226 |
| 120 | 6 | 7.2 | 13.27 | 100.54 ±1.3750 | 1.367 |

*Average of three determinations
**percentage relative standard deviation.

**Ruggedness**

It is defined as the reproducibility of the results when the method is performed under the variant conditions. This includes different analysts, laboratories instrument and temperature etc. ruggedness was determined between two different analysts. The value % RSD was found to less than 2 were shown in table-5.

**Table 5: Determination of Ruggedness results for Abiraterone acetate at 248-258nm by Area under curve.**

| Analysts | Analyst-1 | Analyst-2 |
|---|---|---|
| **Mean Absorbance** | 0.168 | 0.184 |
| **±Standard deviation*** | 0.001633 | 0.000816 |
| **%RSD**** | 0.972 | 0.443 |

*Average of three determinations
**percentage relative standard deviation.

**Limit of Detection and Limit of Quantification**

Limit of detection is an individual analytical method in which the smallest amount of analyte in a sample can be reliably detected by the analytical method.

Limit of quantification is an individual analytical procedure in which the smallest amount of analyte in a sample can be quantitatively determined.

The LOD and LOQ were calculate by using the following formula.
LOD= 3.3(SD)/S and LOQ= 3(LOD)
LOD and LOQ value of Abiraterone acetate were found to be 0.1278 and 0.3835 µgm/ml

**CONCLUSION**

The present analytical method was validated as per the ICH guidelines and met the acceptance criteria. It was concluded that the developed analytical method was simple, accurate, economical, specific and sensitive and can be applied for the routine analysis of Abiratirone acetate in bulk drug and its pharmaceutical dosage forms.

**REFERENCES**

1. https://pubchem.ncbi.nlm.nih.gov/compound/Abiraterone-acetate
2. Reddy S, Thomas L, Ramanna L, Mukhopadhyay A, Thangam S. Estimation of Abiraterone in human plasma by liquid chromatography tandem mass spectrometry. ACTA Pharmaceutica Sciencia, 2018; 56(1).
3. Mukthinuthalapati Mathrusri Annapurna, Debi Prasad Pradhan and Routhu Krishna Chaitanya. New spectrophotometric techniques for the determination of Abiraterone acetate in tablets. JCPS., 2017; 10(2): 769-71.
4. Arun kumar, S Ganapaty, G.V. Radha. Analytical method development and validation for the estimation of Abiraterone acetate in pharmaceutical formulation by UV and RP-HPLC. Int J Pharm Bio Sci., 2016; 7(2): 57-61.
5. Kumar SV, Rudresha G, Gurav S, Zainuddin M, Dewang P, Kethiri RR, Rajagopal S, Mullangi R. Validated RP-HPLC/UV method for the quantitation of abiraterone in rat plasma and its application to a pharmacokinetic study in rats. Biomedical Chromatography, 2013 Feb; 27(2): 203-7.
6. Smriti B, Sushmitha G, Muddu K, SG V. Novel RP-HPLC method for the quantification of Abiraterone acetate. Journal of Global Pharma Technology, 2016; 9(8): 01-9.
7. Annapurna MM, Pradhan DP, Routhu KC. Stability Indicating RP-HPLC method for the determination of Abiraterone (An Anti-Cancer Drug). Research Journal of Pharmacy and Technology, 2018; 11(7): 3007-12.
8. Gong A, Zhu X. β-cyclodextrin sensitized spectrofluorimetry for the determination of

abiraterone acetate and abiraterone. Journal of fluorescence, 2013 Nov 1; 23(6): 1279-86.
9. Smriti B, Sushmitha G, Muddu K, SG V. Novel RP-HPLC method for the quantification of Abiraterone acetate. Journal of Global Pharma Technology, 2016; 9(8): 01-9.
10. Benoist GE, van der Meulen E, Lubberman FJ, Gerritsen WR, Smilde TJ, Schalken JA, Beumer JH, Burger DM, van Erp NP. Analytical challenges in quantifying abiraterone with LC–MS/MS in human plasma. Biomedical Chromatography, 2017 Nov; 31(11): e3986.
11. Kuna AK, Seru Ganapaty and Gadela V Radha. Analytical Method Development and Validation for the Estimation of Abiraterone and its Impurity in Pharmaceutical Formulation by RP-HPLC. Scholar Research library. Der Pharmacia Lettre, 2018; 10(9): 19-31.
12. Gadhave R.V, Tamnar A.B, Bansode A.S, Choudhari V. P. Stability indicating RP-HPLC-PDA method for determination of Abiraterone acetate and characterization of its base catalyzed degradation product by LC-MS. Int J Pharm Pharm Sci., 2016; 8(2): 76-81.
13. M. Ramesh Babu, V. Umamaheswara rao. Stability indicating method development and validation for the estimation of residue of Abiraterone by HPLC. Int J Pharm, 2016; 6(2): 267-76.