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Research

A New Rp-Uplc Analytical Method Development And Validation Of Abiraterone Acetate In Bulk And Its Pharmaceutical Dosage Forms.

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Abstract

A new precise, accurate, rapid method has been developed for the estimation of Abiraterone acetate in bulk and its pharmaceutical dosage form by UPLC. From the above experimental results and parameters it was concluded that, this newly developed method for the estimation Abiraterone acetate was found to be simple, precise, accurate and high resolution and shorter retention time makes this method more acceptable and cost effective and it can be effectively applied for routine analysis in research institutions, quality control department in meant in industries, approved testing laboratories studies in near future. From results the proposed method is highly sensitive, precise and accurate and it successfully applied for the quantification of API content in the commercial formulations of Abiraterone acetate Educational institutions and Quality control laboratories.

Keywords: Diabetes mellitus, Herbal medicine, *Anchusa Officinalis*, Alloxan, Anti diabetic activity.

INTRODUCTION

Ultra Performance Liquid Chromatography

Chromatography is a non-destructive procedure for resolving a multi-component mixture of traces, minor or constituents in to individual fractions. It is a method of separating a mixture of components in to individual components through a porous medium under the influence of solvent[1].

For many years, researchers have looked at "fast LC" as a way to speed up analyses. The need for speed, the availability of affordable and easy to use mass spectrometers. Smaller columns and faster flow rates (amongst other parameters) have been used. Elevated temperature, having the dual advantages of lowering viscosity, and increasing mass transfer by increasing the diffusivity of the analytes, has also been investigated[2-4]. However, using conventional particle sizes and pressures, limitations are soon reached and compromises must be made, sacrificing resolution[5].

HPLC technology simply doesn't have the capability to take full advantages of sub-2µm particles. UPLC can be regarded as new invention for liquid chromatography[6]. UPLC refers to Ultra Performance Liquid Chromatography. UPLC brings dramatic improvements in sensitivity, resolution and speed of analysis can be

calculated. It has instrumentation that operates at high pressure than that used in HPLC & in this system uses fine particles(less than 2.5µm) & mobile phases at high linear velocities decreases the length of column, reduces solvent consumption & saves time[7].

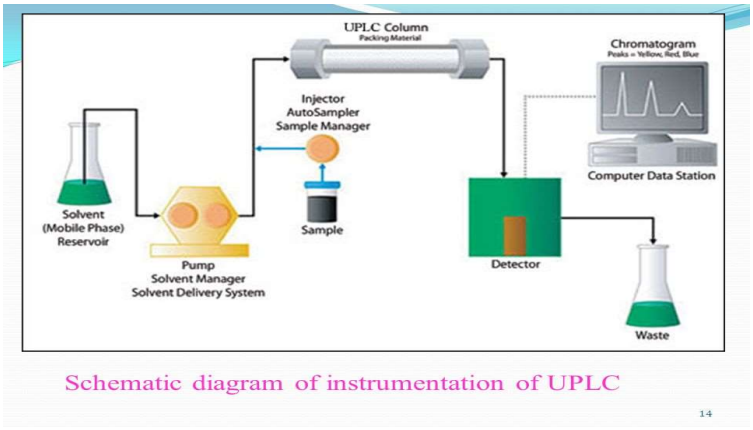
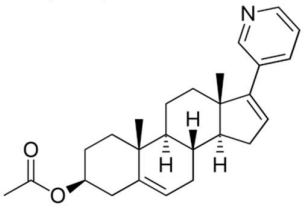


Fig 1: Schematic diagram for UPLC instrument

DRUG PROFILE

Abiraterone Acetate

Abiraterone is a derivative of steroidal progesterone and is an innovative drug that offers clinical benefit to patients with hormone refractory prostate cancer. Abiraterone is administered as an acetate salt prodrug because it has a higher bioavailability and less susceptible to hydrolysis than abiraterone itself.



Chemical structure of Abiraterone Acetate

IUPAC Name: [(3*S*,8*R*,9*S*,10*R*,13*S*,14*S*)-10,13-dimethyl-17-pyridin-3-yl-2,3,4,7,8,9,11,12,14,15-decah ydro-1*H*-cyclopenta[*a*]phenanthren-3-yl] acetate

Molecular Formula: $C_{26}H_{33}NO_2$

Molecular Weight: 391.555 g/mol g·mol^{-1}

Category: Antineoplastic agent

MATERIAL AND METHODS

Instruments

Table 1: Instruments used

UV-Visible Spectrophotometer	Thermo Electron coorporation
UPLC	Agilent Infinity 1290
Ultra Sonicator	Citizen, Digital Ultrasonic Cleaner
pH meter	Thermo
Electronic balance	Mettler Toledo
Syringe	Hamilton
UPLC Column	Xterra C8(150x4.6mm ID) 5µm

Chemicals

Table 2: Chemicals and Solvents used.

Sodium hydrogen Phosphate Monobasic	Rankem/ AR Grade
Acetonitrile	Merck/ HPLC Grade
Water	Merck/ HPLC Grade
Methanol	Merck/ HPLC Grade
Potassium Dihydrogen ortho phosphate	Rankem/ AR Grade
Dipotassium hydrogen ortho phosphate	Rankem/ AR Grade

Drug samples

Table 3: Drugs used

Abiraterone Acetate(bulk drug)	Gift samples obtained from Celon Pharma
Abiraterone Acetate tablets (Abretone 250 mg)	Celon Pharma

RESULTS AND DISCUSSIONS

Solubility Studies

Table 4: Solubility studies

Solvent Name	Abiraterone acetate
Water	Sparingly Soluble
Methanol	Soluble
Acetonitrile	Soluble
Triethylamine	Soluble
Dimethyl formamide	Soluble

Determination of Working Wavelength (λ_{max})

Preparation of Standard solution

10 mg of Abiraterone acetate was weighed and transferred in to 100 ml volumetric flask and dissolved in methanol and then make up to the mark with methanol and prepare 10 µg /ml of solution by diluting 1ml to 10ml with methanol.

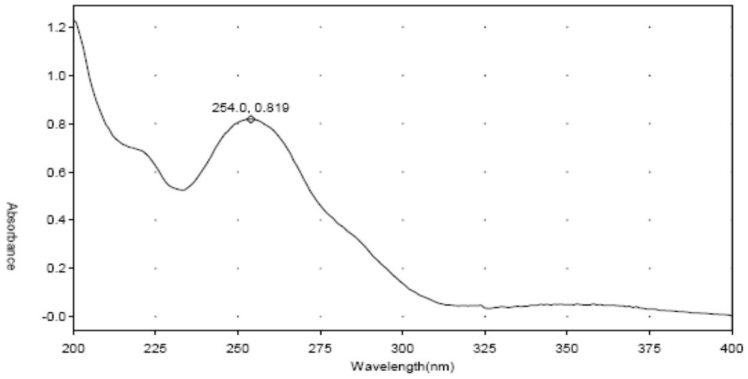


Fig 2: UV-VIS Spectrum of Abiraterone acetate (254 nm)

Method Development Of Abiraterone Acetate

Optimised trial Chromatographic conditions

Column : Acquity CSH C18 Column (100*2.0mm &1.5mm)
Mobile phase : Methanol: ACN: Water
Ratio : 50: 30: 20 v/v/v
Flowrate : 1.0mL/min

Detection wavelength : 254nm
Injection volume : 10µL
Run time : 5min

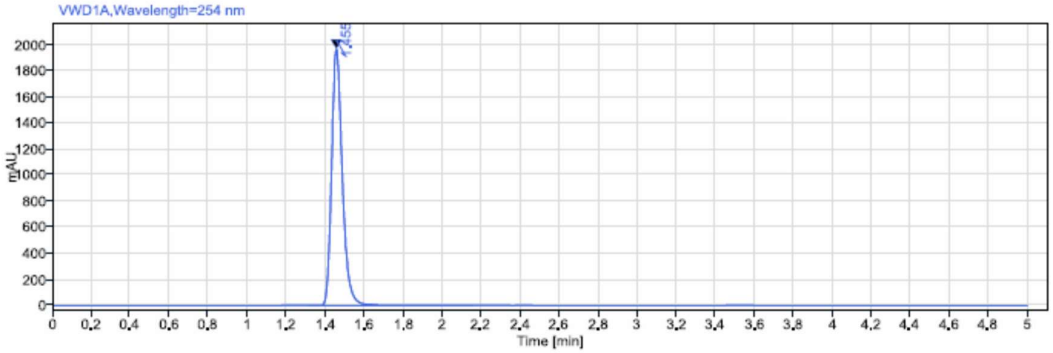


Fig 3: Chromatogram of Optimized trial

Table 5: Results for Optimized Trial

S.NO	Name	Retention Time	Area	Theoretical plates	Tailing Factor
1	Abiraterone acetate	1.455	7544.47	3587	1.25

- All the system suitability requirements were met.
- The efficiency was more than 2000 for Abiraterone acetate
- Hence this method was optimized.

ASSAY

Table 6: Results for Abiraterone acetate

	Abiraterone acetate	
	Standard Area	**Sample Area**
Injection-1	7579.89	7412.85
Injection-2	7577.75	7424.74
Injection-3	7544.46	7471.67
Injection-4	7539.84	7568.61
Injection-5	7557.43	7554.57
Average Area	7559.874	7486.488
Assay(%purity)	99.02	

Validation
System Suitability& System precision

Table 7: Results for system suitability of Abiraterone Acetate

Injection	RT	Peak area	Theoretical plates (TP)	Tailing factor (TF)
1	1.457	7561.87	3579	1.32
2	1.457	7544.48	3619	1.25
3	1.458	7554.34	3591	1.31
4	1.459	7557.49	3628	1.25
5	1.460	7552.46	3631	1.27
6	1.461	7664.35	3630	1.30
Mean	1.459	7572.498	-	-
SD	0.002	45.368	-	-
%RSD	0.112	0.599	-	-

Method precision

Table 8: Method precision results for Abiraterone Acetate

Abiraterone Acetate		
S.No.	**Rt**	**Area**
1	1.455	7544.47
2	1.455	7540.08
3	1.455	7719.05
4	1.455	7550.07
5	1.454	7534.42
6	1.454	7541.71
avg	1.455	7571.633
Std dev	0.001	72.402
%RSD	0.035	0.956

Linearity and range

Table 9: Linearity Preparations

Preparations	Volume from standard stock transferred in mL	Volume made up in mL (with mobile phase)	Conc. obtained (µg/mL) Abiraterone Acetate
Preparation 1	0.25	10	25
Preparation2	0.50	10	50
Preparation 3	0.75	10	75
Preparation 4	1.0	10	100
Preparation 5	1.25	10	125

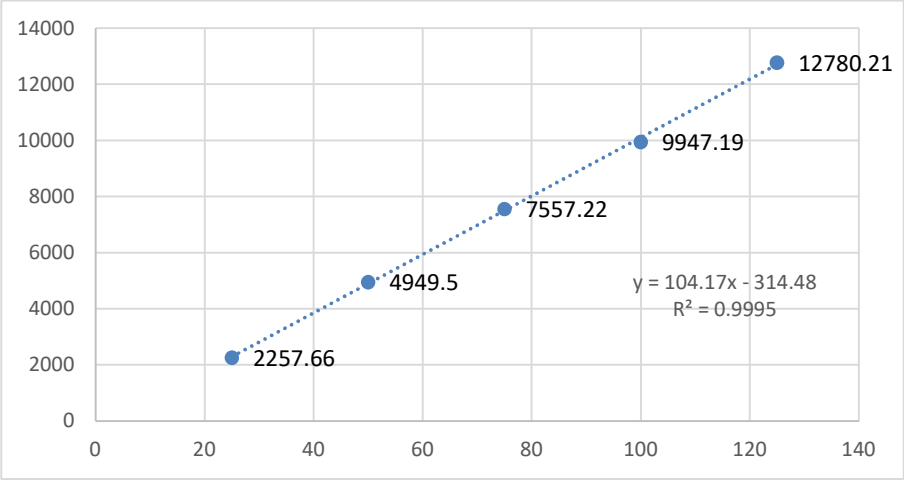


Fig 4: Graph for Linearity data of Abiraterone Acetate

Table 10: Linearity results of abiraterone acetate.

S.No	Parameter	ABIRATERONE ACETATE
1	Correlation coefficient	0.9995
2	Slope	104.17
3	Intercept	314.48

Specificity

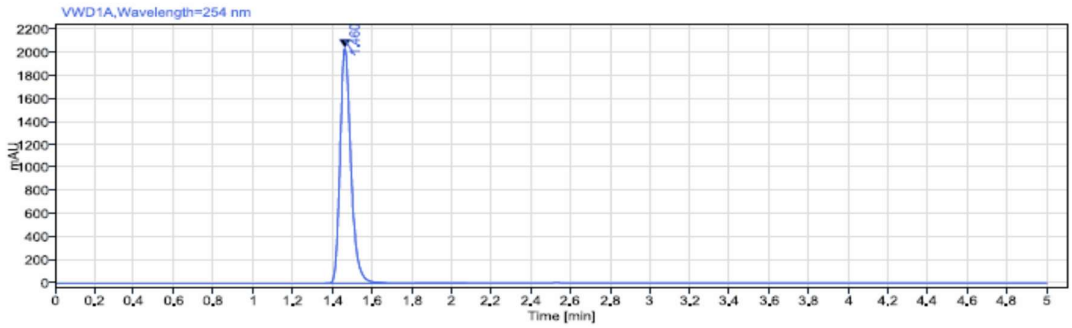


Fig 5: Chromatogram of Specificity Standard

Accuracy

Table 11: Results for Recovery of Abiraterone Acetate

Recovery	Area	Avg Area	% Recovered	% Recovery
	1889.25			
	1878.34			
25	1889.74	1885.78	24.95	99.82
	5667.75			
	5679.65			
75	5681.44	5676.28	75.11	100.15
	9446.25			
	9452.34			
125	9457.22	9451.94	125.08	100.06

Robustness

Table 12: Results for Robustness of Abiraterone Acetate

Chromatographic changes		**Retention time(min)**	**Tailing Factor**	**Theoretical Plates**
Flow rate	0.8	1.463	1.32	3672
((mL/min)	1.2	1.457	1.27	3622
Temperature (°C)	25	1.456	1.24	3675
	35	1.463	1.30	3644

Ruggedness

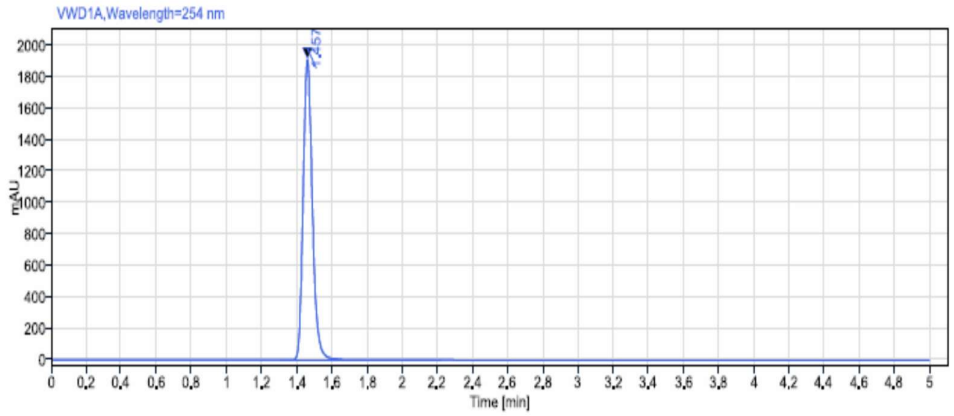


Fig 6: Chromatogram of Analyst-01 standard

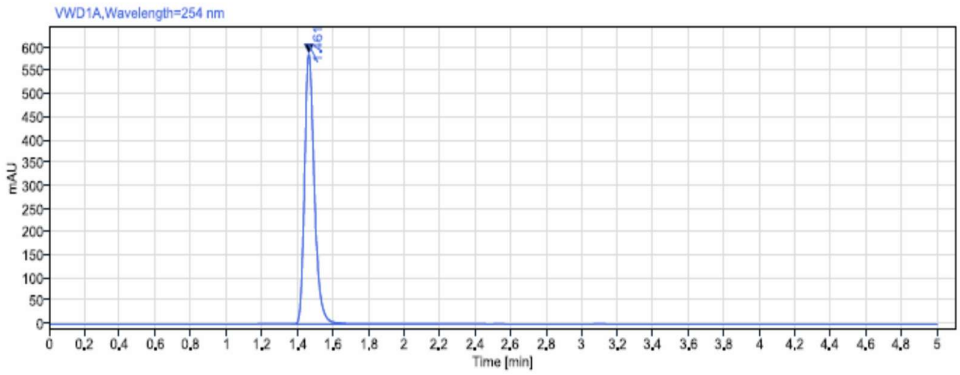


Fig 7: Chromatogram of Analyst-02 standard

Table 13: Ruggedness Results of Abiraterone Acetate

Abiraterone Acetate	**%Assay**
Analyst 01	99.39%
Analyst 02	99.77%
%RSD	0.296 %

Stability Studies

Table 14: Observation: Abiraterone Acetate

Method	**std area**	**Degradation area**	**% Obtained**	**% Degraded**
Peroxide	7557.43	7487.24	99.07	0.74
Photolytic	7557.43	7482.74	99.01	0.80
Acidic	7557.43	7477.27	98.94	0.87
Alkaline	7557.43	7479.37	98.97	0.84
Thermal	7557.43	7481.64	99.00	0.81

CONCLUSION

A new precise, accurate, rapid method has been developed for the estimation of Abiraterone acetate in bulk and its pharmaceutical dosage form by UPLC. From the above experimental results and parameters it was concluded that, this newly developed method for the estimation Abiraterone acetate was found to be simple, precise, accurate and high resolution and shorter retention time makes this method more acceptable and cost effective and it can be effectively applied for routine analysis in research institutions, quality control department in meant in industries, approved testing laboratories studies in near future. From results the proposed method is highly sensitive, precise and accurate and it successfully applied for the quantification of API content in the commercial formulations of Abiraterone acetate Educational institutions and Quality control laboratories.

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