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METHOD DEVELOPMENT AND VALIDATION OF BICAULPAMIDE AND ATENOLOL IN BULK AND IN ITS PHARMACEUTICAL DOSAGE FORMS USING RP- HPLC

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ABSTRACT

A new method was established for simultaneous estimation of Bicalutamide and Atenolol. The chromatographicconditionsweresuccessfullydevelopedfortheseparationofBicalutamide and Atenolol by using Agilent C18 5µm (4.6*250mm) column, flow rate was 1ml/min, mobile phase ratio was Water: ACN (70:30%v/v), detection wavelengthwas 254nm.

KEY WORDS: AgilentC18, Bicalutamide and Atenolol, RP-HPLC method.

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INTRODUCTION

"Bicalutamide is a non steroidal peripheral androgen receptor inhibitor1 It competitively inhibits the action of androgens by binding to cytosol androgen receptors in the target tissue It is Literature survey reveals that various spectrophotometric2 and HPLC methods3 4 have been reported for the determination of bicalutamide in pure and pharmaceutical dosage forms In this study a simple rapid accurate sensitive and precise HPLC method was developed for the estimation of bicalutamide in pharmaceutical dosage forms" " Bicalutamide is a Non steroidal antiandrogen receptor It competitively inhibits the action of androgens by binding to cytosol androgen receptors in the target tissue It is Literature survey reveals that various spectrophotometric and HPLC methods have been reported for the determination of bicalutamide in pure and pharmaceutical dosage forms In this study a simple rapid accurate sensitive and precise HPLC method was developed for the estimation of bicalutamide in pharmaceutical dosage" . " Atenolol ATL is a cardioselective β blocker It is reported to lack intrinsic sympathomimetic activity and membranestabilizing properties This drug is used to treat numerous cardiovascular disorders for example hypertension angina pectoris cardiac arrhythmias and myocardial infarction It is official in USP IP and BP." Analytical chemistry is a branch of chemistry involved in separating identifying and determining the relative amounts of the components making up a sample of matter It is mainly involved in the qualitative analysis or detection of compounds and quantitative analysis of the compounds A qualitative method yields information about the identity of atomic or molecular species or functional groups in the sample A quantitative method in contrast provides numerical information as to the relative amount of one or more of these components." A variety of methods

are available for analyzing pharmaceutical compounds High Performance Pressure Liquid Chromatography HPLC is one of the best methods of choice for analyzing a variety of natural and synthetic compounds It is because it offers high performance over ambient pressureThe phenomenal growth in chromatography is largely due to the introduction of the technique called high pressure liquid chromatography which is frequently called high performance liquid chromatography both are abbreviated as HPLC It allows separations of a large variety of compounds by offering some major improvements over the classical column chromatography TLC GC and it presents some significant advantages over more recent techniques such as supercritical fluid chromatography SFC capillary electrophoresis CE and electro kinetic chromatography." Effective and fast method development is of paramount importance throughout this drug development life cycle This requires a thorough understanding of HPLC principles and theory which lay a solid foundation for appreciating the many variables that are optimized during fast and effective HPLC method development and optimization Chromatographic separations are based on a forced transport of the liquid mobile phase carrying the analyte mixture through the porous media and the differences in the interactions at analytes with the surface of this porous media resulting in different migration times for a mixture components." High surface area of the interface between mobile and stationary phases is essential for space discrimination of different components in the mixture Analyte molecules undergo multiple phase transitions between mobile phase and adsorbent surface" "Average residence time of the molecule on the stationary phase surface is dependent on the interaction energy For different molecules with very small interaction energy difference the presence of significant surface is critical since the higher the number of phase transitions that analyte molecules undergo while moving through the chromatographic column the higher the difference in their retention (1-4)."

Literature review reveals that there's no analytical technique reportable for the analysis of Bicalutamide and beta-adrenergic blocker by synchronous estimation by RP-HPLC. Photometer, HPLC and HPTLC ar the reportable analytical ways for compounds either one by one or together with different dose kind. Hence, it absolutely was felt that, there's a necessity of latest analytical technique development for the synchronous estimation of Bicalutamide and beta-adrenergic blocker in pharmaceutical dose kind. Present work is aimed to develop a replacement, simple, fast, rapid, accurate, economical and duplicable RP-HPLC technique for the synchronous analysis of Bicalutamide and beta-adrenergic blocker. The developed technique is going to be valid in keeping with ICH pointers.

MATERIALS AND METHODS (5-8)

Preparation of the individual Bicalutamide standard preparation

10mg of Bicalutamide working standard was accurately weighed and transferred into a 10ml clean dry volumetric flask and about 2ml of DMF is added. Then it is sonicated to dissolve it completely and made volume upto the mark with the diluant.(Stock solution). Further 10.0 ml from the above stock solution is pipette into a 100ml volumetric flask and was diluted upto the mark with diluant.

Preparation of the individual Atenolol standard preparation

10mgofAtenolol working standard was accurately weighed and transferred into a 10ml clean dry volumetric flask and about 2ml of DMF is added.Then it is sonicated to dissolve it completely and made volume upto the mark with the diluant.(Stock solution). Further 10.0 ml from the above stock solution is pipette into a 100ml volumetric flask and was diluted upto the mark with diluents.

RESULTS AND DISCUSSION

Wavelength Detection

The detection wavelength was chosen by dissolving the drug in mobile section to induce a amount of 10µg/ml for individual and mixed standards. The ensuing resolution was scanned in U.V vary from 200-400nm.

The overlay spectrum of Bicalutamide and beta-adrenergic blocking agent was obtained and also the isobestic purpose of Bicalutamide and beta-adrenergic blocking agent showed absorbance's maxima at 254 nm. The spectrums are shown in Fig-1.

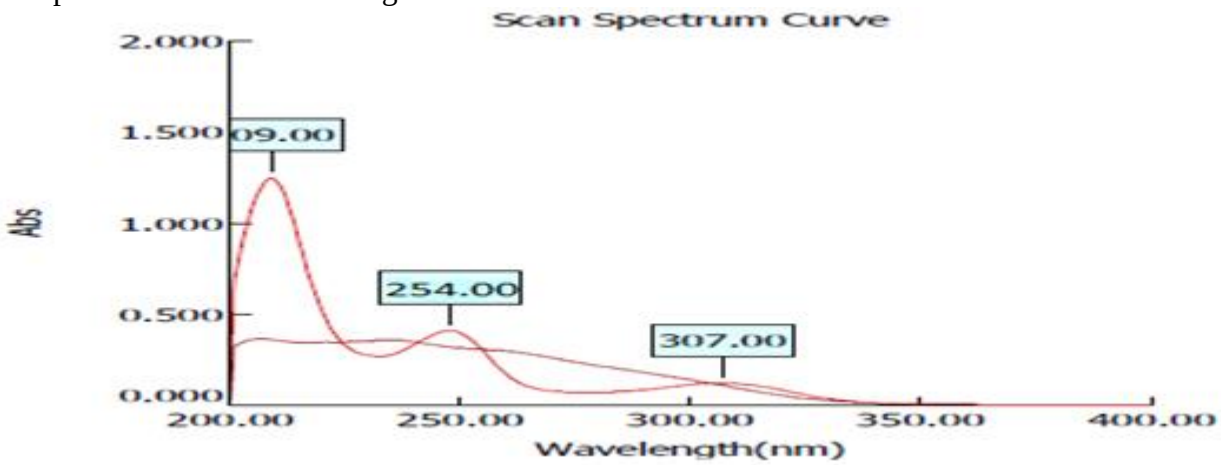

Fig-1 Overlay spectrum of Bicalutamide and Atenolol

Assay Calculations for Bicalutamide and Atenolol

The assay study was performed for the Bicalutamide and beta-adrenergic blocking agent. every 3 injections of sample and commonplace was inject into natural process system. The chromatograms area unit shown in Fig-2.

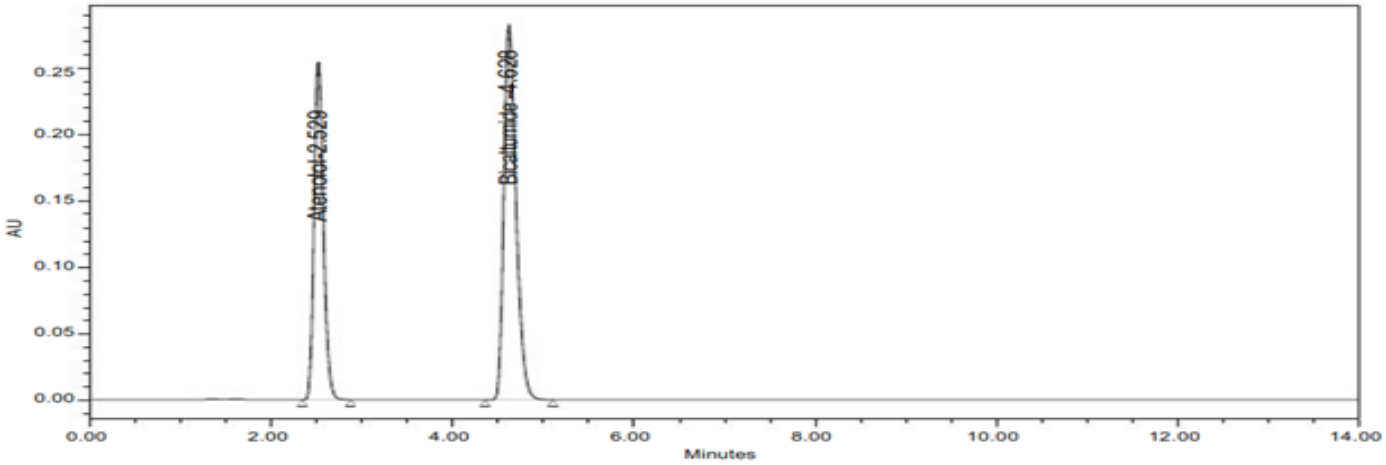

Fig-2 Chromatogram showing sample injection

Accuracy

The accuracy study was performed for five hundredth, 100 percent and a hundred and fifty you look after Bicalutamide and beta-adrenergic blocker every level was injected in triplicate into natural action system and results are given in table-1 and 2.

Table-1 Accuracy results of Bicalutamide

%Concentration (at specificationLevel)	Area	Amount added(m)	Amount found(m)	% Recovey	Mean Recovery
50%	1426646	5	4.9	101.8%	102.5%
100%	2551005	10	9.98	99.9%	
150%	2139845	15	15.0	100.0%	

Table-2 Accuracy results of Atenolol

%Concentration(at specification level)	Area	Amount Added(mg)	Amount Found(mg)	%Recovery	Mean Recovery
50%	975578	5	5.0	101.3%	101.0%
100%	1718370	10	9.96	99.6%	
150%	1465857	15	14.9	99.3%	

The LOD was performed for Bicalutamide and Atenolol was found to be 3.1and 3.02 respectively. The LOQ was performed for Bicalutamide and Atenolol was found to be 10.1 and 10 respectively**.**

Linearity

The one-dimensionality study was performed for the concentration of 100ppm to 500ppm and1ppm to 5ppm level. every level was injected into action system. the world of every level was used for calculation of correlation. Results square measure tabulated in table-3 and 4 and fig-3 and 4.

Table-3 Linearity Results of Atenolol

S.No	Linearity Level	Concentration	Area
1	I	20 ppm	471543
2	II	40 ppm	656277
3	III	60 ppm	794999
4	IV	80 ppm	946124
5	V	100 ppm	1002139
Correlation Coefficient			0.999

Table-4 Linearity Results of Bicalutamide

S.No	Linearity Level	Concentration	Area
1	I	20 ppm	471543
2	II	40 ppm	656277
3	III	60 ppm	794999
4	IV	80 ppm	946124
5	V	100 ppm	1002139
Correlation Coefficient			0.999

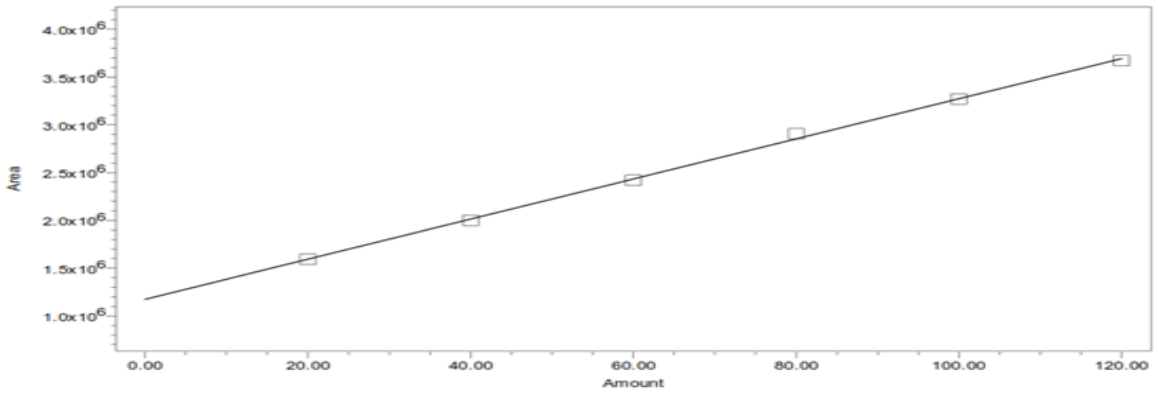

Fig-3 Calibration curve of Atenolol

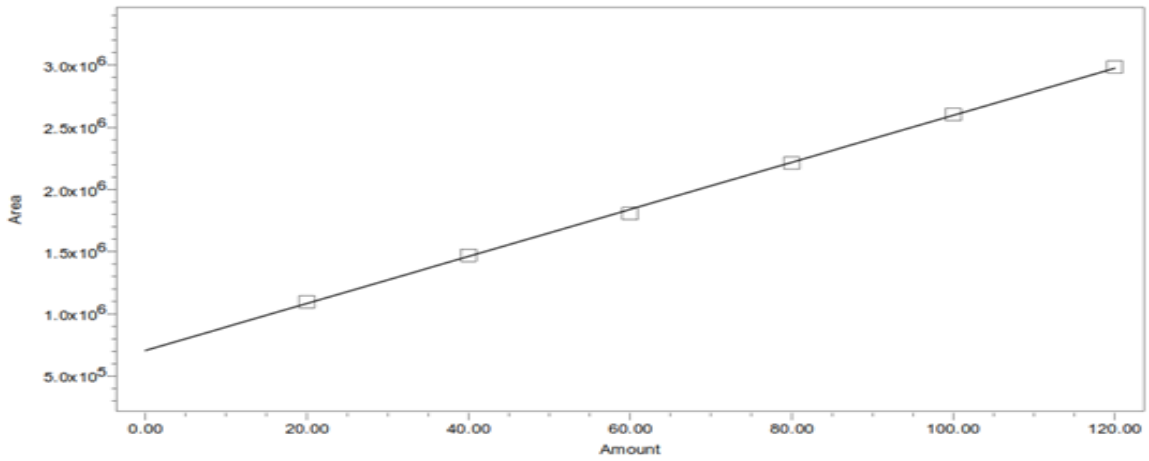

Fig-4 Calibration curve of Bicalutamide

The one-dimensionality study was performed for concentration vary of 20µg - 100µg and 20µg-100µg of Bicalutamide and beta-adrenergic blocking agent and therefore the parametric statistic was found to be 0.999 and 0.999. On analysis of the higher than results, it may be ended that the variation in rate affected the tactic considerably. Therefore it indicates that the tactic is strong even b y modification within the rate ±0.2ml/min.

CONCLUSION

The proposed HPLC method was found to be simple, precise, accurate and sensitive for the determination of Bicalutamide and Atenolol in pharmaceutical dosage forms. Hence, this method can easily and conveniently adopt for routine quality control analysis of Bicalutamide and Atenolol in pure and its pharmaceutical dosage forms.

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