ISSN: 0974-6943

Research Article

Simultaneous estimation of Tamsulosin hydrochloride and Dutasteride in combined dosage form by UV spectroscopy method

Pande V.V.*, Jadhav J.N.,* Chandorkar J.G.**

* JSPM's, Jaywantrao Sawant College of Pharmacy & Research, S.No.58, Satavnagar,Handewadi Road, Hadapsar, Pune-411028,India.

** Innovassynth Technologies Ltd, Khopoli, Dist. Raigad.India.

*For correspondence:*Pande V.V,JSPM's,Department of Pharmacutical Chemistry, Jaywantrao Sawant College of Pharmacy & Research, S.No.58, Satavnagar,Handewadi Road, Hadapsar, Pune-411028,India.

*E-mail:*vishalpande_1376@rediffmail.com

Received on:19-08-2008; Accepted on :15-02-2009

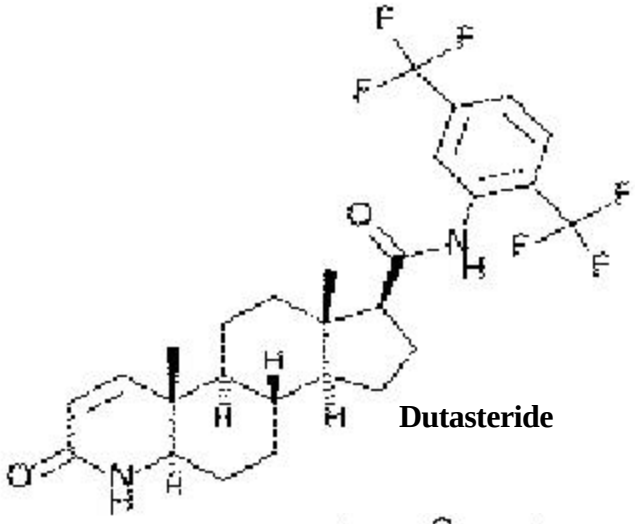
ABSTRACT

Fixed dose combination tablets containing Tamsulosin hydrochloride & Dutasteride are used to treat the symptoms of an enlarged prostate, a condition technically known as benign prostatic hyperplasia or BPH. Several chromatographic methods have been reported for simultaneous estimation of these drugs and individual drug. The drugs individually and in mixture obeys Beer's law over conc. range 0.0347 mg/mL for Tamsulosin hydrochloride (TAM) and for Dutasteride 0.012 mg/mL (DUTA). The mean recoveries from tablet by standard addition method were 99.0% and 99.5 %. The present work reports simple, accurate and precise spectrophotometric method for the simultaneous estimation of Tamsulosin hydrochloride and Dutasteride in combined from tablet dosage form.

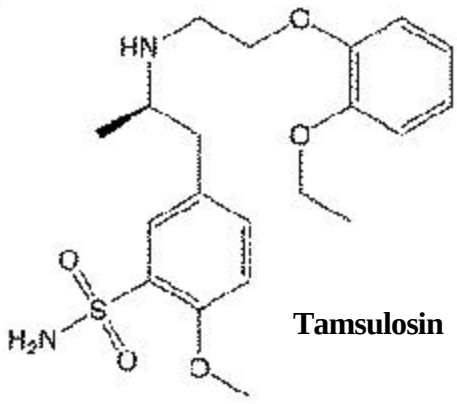
Key words: Tamsulosin hydrochloride (TAM), Dutasteride (DUTA), Benign prostatic hyperplasia or BPH

INTRODUCTION

Tamsulosin hydrochloride is used to treat the symptoms of an enlarged prostate—a condition technically known as benign prostatic hyperplasia or BPH [1]. The walnut-sized prostate gland surrounds the urethra (the duct that drains the bladder). If the gland becomes enlarged, it can squeeze the urethra, interfering with the flow of urine [2]. This can cause difficulty in starting urination, a weak flow of urine, and the need to urinate urgently or more frequently. Tamsulosin hydrochloride does not shrink the prostate. Instead, it relaxes the muscle around it, freeing the flow of urine and decreasing urinary symptoms [3]. Dutasteride is chemically 15a, 17ß)-N-{2, 5, bis (trifluoromethyl) phenyl}-3-oxo-4-azaandrost-1-ene-17-carboxamide. It belongs to class of drugs called 5-alpha-reducactase enzyme that convert testosterone in to dihydrotestosterone. It is used for the symptomatic benign prostatic hyperplasia or BPH in men with an enlarged prostate. Several methods have been cited in various literatures but the prescribed method has unique advantage over it as it has capability of analyzing the product in Bulk and Formulated Dosages [4]. This method can even be employed in routine determination of simultaneous estimation of Tamsulosin hydrochloride and Dutasteride in combined from tablet dosage form [5-7].



Dutasteride



Tamsulosin

ISSN: 0974-6943

EXPERIMENTAL

Apparatus

1. Spectrophotometer: - Perkin Elmer
2. Model: - Lambda EZ 210
3. Volumetric flasks: - Amber Glass.
4. Water: - UV Grade.
5. Grade-A pipettes.

Determination of TAM and DUTA in their Combined Dosage Forms.

The multi-component spectrophotometric mode of estimation is based on comparing spectral data of mixed standard solutions with that sample at selected wavelengths (one less than total number of standards). The necessary requirements of the method, obeyance of Beer's law and additively of absorbance at all selected wavelengths were followed by the drugs. Six mixed standard solutions were prepared containing TAM (0.0347 mg/mL) and DUTA (0.012 mg/mL) in 1:12 ratio. Tablet powder extracted with methanol and appropriately diluted to contain about 0.0347 mg/mL of TAM. In the scanning range 200-400 nm, five wavelengths (200, 240, 280, 320, 360, 400 nm) were selected in multi-component mode of spectrophotometer and the conc. of each component of all six standards were entered in it. The mixed standards were then scanned followed by samples over the scanning range. The conc. of samples were directly displayed after due processing. The results are summarized in Table-1.

Reagent and Chemicals -

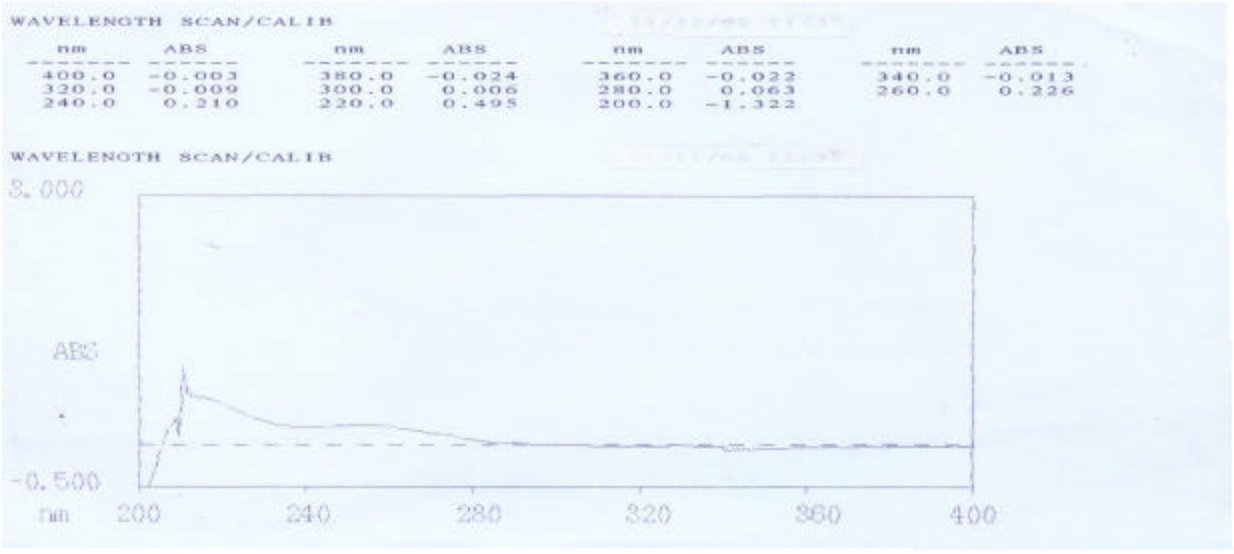
Analytically pure Tamsulosin Hydrochloride & Dutasteride were obtained as gift samples from Intas Pharmaceutical Ltd, Ahmadabad along with certificate of analysis. Analytical grade methanol is used procured from RFCL Ltd. New Delhi.

Assay Results of Combined Dosage Form Using Proposed Method

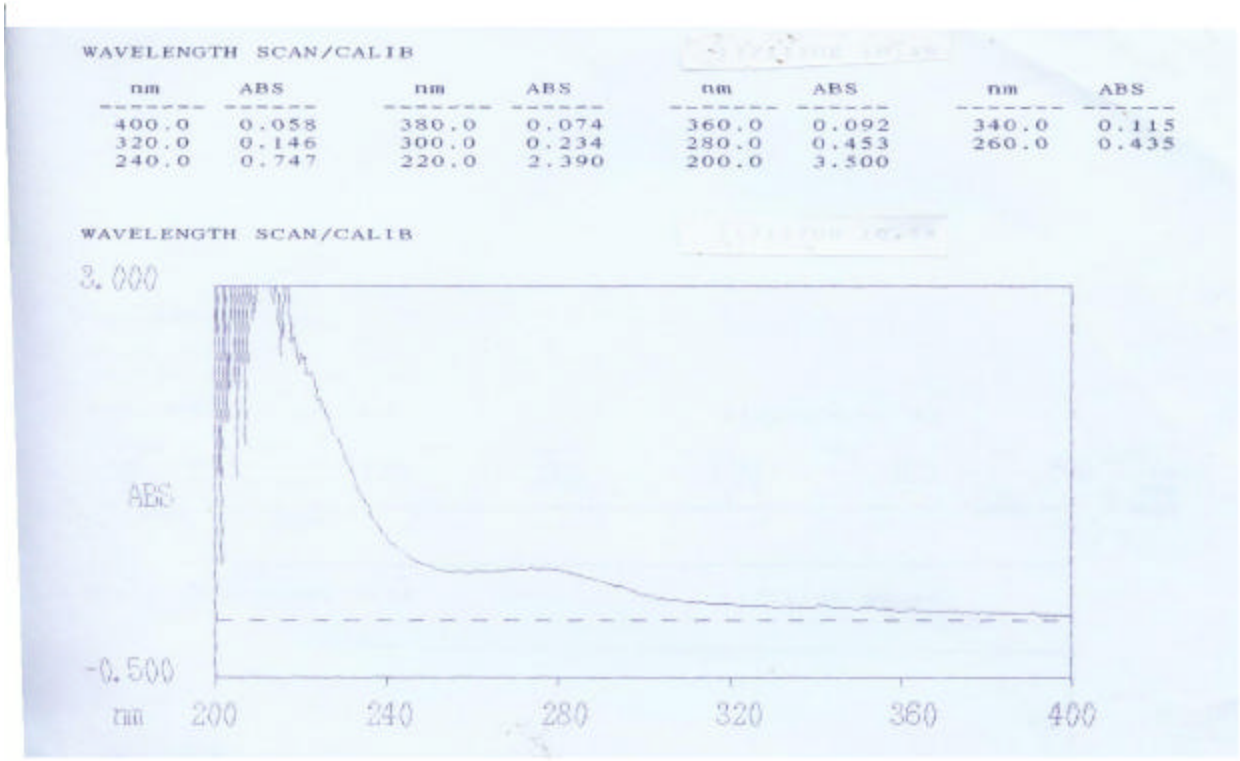
Sr. No.	Sample	Labelled Amount (mg)		% Recovery	
		TAM	DUTA	TAM	DUTA
1	Standard	99%	99.5%	——	——
2	Tablet Sample	0.4 mg	0.5 mg	0.3954 mg	0.5005 mg

Spectra of Combined Drugs:

Spectra of Dutasteride



Spectra of Tamsulosin Hydrochloride



RESULTS AND DISCUSSION

The spectrophotometric method has been based on exploitation of multi-component mode of double beam spectrophotometer. Methanolic mixed standard and sample solutions were scanned over 200-400 nm range (with sampling wavelengths 200, 240, 280, 320, 360, 400 nm). The drugs individually and in mixture obey Beer's law over conc. Range 0.0347 mg/mL for Tamsulosin and for dutasteride 0.012 mg/mL at all five sampling wavelengths. The mean recoveries from tablet by standard addition method were 99.0% and 99.5 %. The method is suitable for simultaneous estimation of Tamsulosin and dutasteride from tablet dosage form.

CONCLUSION

The proposed spectrophotometric method is accurate, precise and also simple, rapid and economic and may be adopted for routine simultaneous estimation of Tamsulosin and dutasteride from tablet dosage form.

ACKNOWLEDGEMENT

We sincerely thanks to management of JSPM Pune & Innovassynth Technologies Ltd, Khopoli, Dist. Raigad for their cooperation regarding fulfillment of this research work.

REFERENCES

1. Ichioka K, Ohara H, Terada N, Matsui Y, Koji Y, Terai A and Arai Y , Long-term treatment outcome of tamsulosin for benign prostatic hyperplasia., *International Journal Of Urology* Vol **11**: (10), 2004 Pg no 870.
2. Kakizaki H, Ameda K, Kobayashi S, Tanaka H and Shibata T, Tomohiko K, Urodynamic effects of a1-blocker tamsulosin on voiding dysfunction in patients with neurogenic bladder. *International Journal Of Urology* Vol **10**(11), 2003 Pg No. 576.
3. Matsushima H, Takanuki K, Kamimura H, Watanabe T and Higuchi S, Highly sensitive method for the determination of tamsulosin hydrochloride in human plasma dialysate, plasma and urine by highperformance liquid chromatography-electrospray tandem mass spectrometry. *Drug Metabolism* Vol **26**(3) 2003 Pg No. 240-245.
4. Michel M, Bressel H, Goepel M and Rübben H A 6-month large-scale study into the safety of Tamsulosin. *British Journal Of Clinical Pharmacology* Vol . **51**(6): 2001 Pg No 609.
5. Mohanty N, Nayak R, Malhotra V and Arora R A double-blind placebo controlled study of tamsulosin in the management of benign prostatic hyperplasia in an Indian population. *Annual surgery* Vol **7**(3): 2003 Pg No 88.
6. Rolan P, Terpstra I, Clarke C, Mullins F and Visser J, A placebo-controlled pharmacodynamic and pharmacokinetic interaction study between tamsulosin and acenocoumarol. *British Journal Of Clinical Pharmacology* Vol **55**(3): 2003 Pg no 314.
7. Schäfers R, Fokuhl B, Wasmuth A, Schumacher H, Katsunari T, Christian de Mey, Thomas P and Martin C M Differential vascular a1-adrenoceptor antagonism by tamsulosin and terazosin. *British Journal Of Clinical Pharmacology*. Vol **47**(1):1999 Pg no 678.

Source of support: Nil, Conflict of interest: None Declared