PLASYS300®, THE NEW COMPLEX FOR PROSTATE HEALTH

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INTRODUCTION

Benign prostatic hyperplasia (BPH) leads to obstructive urinary symptoms experienced to some extent by most men over 50 years old (Berry et al., 1984; Thorpe & Nea., 2003).

Test and diagnosis consist of a physical exam focused on the urinary tract, blood and urine analysis, and digital rectal exam (**Figure 1**). The pharmacotherapy treatments are via 5α-reductase inhibitors (5-ARIs) or Alpha-blockers, but both treatments show several undesirable side effects (Robert et al., 2011; **Table 1**).

Plasys300® is a natural complex enriched in phytosterols, chiefly β-sitosterol and essential amino-acids with proven effectiveness in ameliorating prostate discomfort symptoms: diminish IPSS score, urinary flow rate, irritating (itching) and obstructive symptoms (Berges et al., 1995; Dutkiewicz, 1996, Elist, 2006).

OBJECTIVES

The main objective of this work was to test the effect in vitro of the bioactive components of Plasys300® in human cells from prostatic adenocarcinoma, PC3 cell line, and to evaluate cell viability and proliferation.

Table 1. FDA-Approved drugs to treat BPH

Alpha antagonists	**Side effects**
Alfuzosin	Retrograde ejaculation
Doxazosin	Erectile dysfunction
Silodosin	Asthemia
Tamsulosin	Dizziness
Terazosin	Orthostatic hypotension
	Nasal congestion
5-alpha-Reductase Inhibitors	**Side effects**
Dutasteride	Reduced libido
	Erectile dysfunction
Finasteride	Decreased ejaculate volume
	Breast tenderness

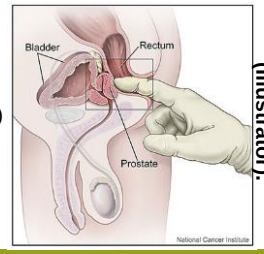


Figure 1. Digital Rectal Exam (DRE) **Alan Hoofring (Illustrator).**

METHODOLOGY

Sterols (non-saponified fractions) from Plasys300® samples were extracted following the procedure described by Gil-Ramirez et al. (2013). Non-saponified fractions were prepared at 12 mg/mL in a chloroform:methanol (2:1 v/v) solution including hexadecane as internal standard and submitted to GC-MS-FID analysis according to Teichmann et al. (2007).

Proliferation assays were performed in PC-3 cultures using increasing concentrations of Plasys300® (saponified or non-saponified fractions). MTT-assay (3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyl tetrazolium-bromide (Sigma-Aldrich), was performed according to the manufacturer's instructions. Statistical analysis was performed by the unpaired Student's t-test. The significance level was set as P=0.05.

PHARMACTIVE BIOTECH PRODUCTS

a natural difference

RESULTS

Phytosterols act as 5-alpha-Reductase Inhibitors, chiefly β-sitosterol (**Figure 2**), which is effective in relieving BPH symptoms (Berges et al., 2000).
Sterol fraction of Plasys300® induced anti-proliferation of human prostatic (PC-3) cells in a dose-dependent manner. At 10 µg/mL it inhibited cell proliferation by 50% whereas at its highest concentration, 50 µg/mL the inhibition held up at 65%

Figure 2. Gas-FID chromatogram of Plasys300®

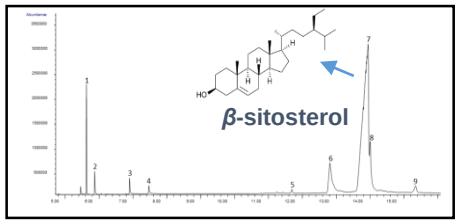
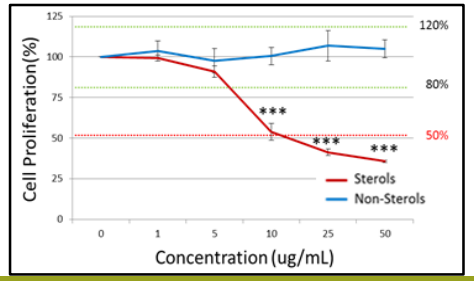


Figure 3. Effects of Plasys300® on Cell Proliferation



CONCLUSIONS

The fraction corresponding to phytosterols in Plasys300® has a significant effect on cell viability at concentrations of 10 ug / mL and above.

The slope of reduction observed from this concentration suggests that Plasys300® is not cytotoxic but has an antiproliferative effect in a prostatic cancer cell line.

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