Ain Shams University
Faculty of Science
Chemistry Department

Analytical study for the determination of some drugs used in treatment of masculinity diseases

By

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(M. Sc. Degree, Analytical Chemistry, Cairo University, 2012)

To

Chemistry Department

Faculty of Science

Ain Shams University

For

Ph.D. in Science
(Analytical Chemistry)

2016

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A thesis submitted for Ph.D. in Science
(Analytical Chemistry)
2016

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ACKNOWLEDGEMENT

I would like to express my deepest appreciation to my supervisors, ***Prof. Dr. Eglal Mariam Raymond Souaya*** (department of Chemistry, faculty of Science, Ein-Shams university), for her continuous help and invaluable assistance, support and guidance. Deepest gratitudes are also due to my co-supervisors ***Prof. Dr. Fatma M. Abdel-Gawad and Assis. Prof. Mona Mohammed Abdel-Moety*** **(NODCAR)** for the unforgettable help, inspiration and support which they both consistently offered me throughout the entire PhD work.

I am grateful to ***Assis. Prof. Ali Kamal Attia*** for his unforgettable help in my work.

To the memory of my lovely father, may Allah rest his soul in peace and show his mercy on him. To my beloved mom, my sincere husband, my sweet kids, my sisters and my brother thank you for being in my life. Nothing would be possible without each and every one of you.

Lastly, I am deeply grateful and thankful for my colleagues in NODCAR. Their kindness and support was always given in abundance. Also, special thanks to ***Eman Fathy Mohamed*** and ***Rasha Elgohary*** for their continuous and valuable advices, they are true friends of mine and like sisters to me.

Ethar Abd Elraouf Mohamed

ABSTRACT

Name: Ethar Abdelraouf Mohamed Soliman

Title of thesis: Analytical study for the determination of some drugs used in treatment of masculinity diseases.

Degree: Ph.D., Faculty of science, Ain Shams University, 2016.

Four simple, accurate and sensitive methods were developed for the determination of two drugs used in treatment of masculinity diseases which are vardenafil (VAR) and dapoxetine (DAP) hydrochlorides in bulk powder and pharmaceutical formulations. Method I is based on spectrophotometric methods for simultaneous determination of VAR and DAP hydrochlorides in combined dosage form. These methods include : simultaneous equations, dual wave length, zero- crossing derivatives and first derivative of ratio spectrophotometry. Method II was thermal analysis. In this method thermal analysis techniques have been used to study the thermal behavior of VAR and DAP. This study has been confirmed using semi-empirical molecular orbital calculations. Method III involves the direct titration of VAR and DAP with NBS and the end point is determined potentiometrically. The proposal of the oxidation reaction pathway is postulated. Method IIII is high performance liquid chromatography (HPLC). Isocratic reversed phase HPLC method was applied for the simultaneous determination of VAR and DAP using C_8 column with UV detection at 230 nm, mobile phase phosphate buffer : acetonitrile (50: 50 v/v) and flow rate 1.5 min/mL. The analytical validations and recovery studies were performed to confirm the accuracy of the proposed methods. The methods were validated according to the International Conference on Harmonization (ICH) guideline.

Keywords: Vardenafil, Dapoxetine, Spectrophotometry, Thermal analysis, Potentiometric titration, High performance liquid chromatography, Bulk powder, Pharmaceutical formulations.

AIM OF THE PRESENT WORK

Vardenafil (VAR) and Dapoxetine (DAP) Hydrochlorides are very effective pharmaceutical formulations which are widely used in treatment of the two most prevalent masculinity dysfunctions which are erectile dysfunction (ED) and premature ejaculation (PE).

Recently, VAR has an official method for its determination, while DAP has not any pharmacopoeia method. But due to their therapeutic importance several analytical methods have been reported for their quantitative determination in bulk and/or dosage forms, either singly or in combination to each other. This is enhance the development of simple, accurate, sensitive and applicable methods for their determination in pure and dosage forms

The proposed methods for the simultaneous determination of VAR and DAP which are:

- Spectrophotometry.
- Thermal analysis.
- Potentiometric titration.
- High performance liquid chromatography (HPLC).

The common, availability of the instrumentation, simplicity of procedures, speed, precision and accuracy of the suggested methods make these methods more valuable and attractive for use.

- All the proposed methods were validated as per ICH guidelines.

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