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Analytical techniques for udenafil estimation: A comprehensive review

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Abstract
Clinical studies have confirmed that the various analytical techniques are used to develop a rapid and accurate Udenafil analytical procedure. These techniques are most commonly used in the pharmaceutical industry that produces a significant amount of organic toxic waste at various phases of the manufacturing process. Therefore, it is essential that the Green analytical chemistry (GAC) principles should be applied to pharmaceutical analysis. This analysis confirmed that the procedure is environmentally benign in terms of green solvent use, chemical composition, energy use, and waste generation. In this article, an overview of green strategies that can be easily applied in developing eco-friendly analytical methods for the estimation of Udenafil in formulations by using green solvents like Ethanol is given.

Keywords: Udenafil, high-performance liquid chromatography (HPLC), green analytical chemistry (GAC), eco-friendly analytical methods, green solvent, ethanol

Introduction
Udenafil is a benzenesulfonamide derivative with vasodilatory activity and a new phosphodiesterase type 5 (PDE5) inhibitor used in the treatment of erectile dysfunction (ED). Udenafil is one of phosphodiesterase type five (PDE-5) inhibitor. In the treatment of sexual ED, PDE-5 inhibitions are the first line of treatment. Among the PDE-5 inhibitor class, Udenafil is a five-new medication that meets a requirement for a multi-molecule with the advantages of the current medications and a tolerable image. Under the trade name Zydena tablet 100 and 200 mg, Udenafil has been registered by the JFDA in the Jordanian market. It is also registered in South Korea, several European nations, and India. Figure 1 shows the udenafil structural formula.

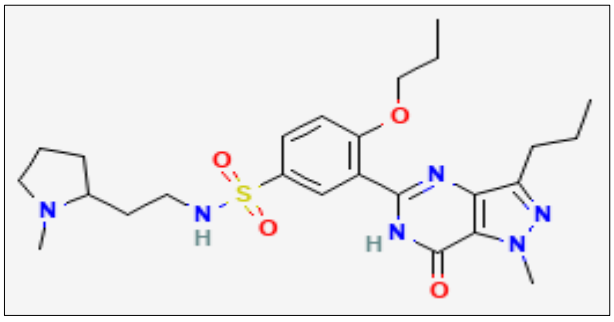

Fig 1: Structure of Udenafil

Chemical name: (5-[2-propyloxy-5-(1-methyl-2-pyrollidinylethyl-amidosulphonyl) phenhyl]-1-methyl-3-propyl-1, 6-dihydro-7H-pyrazolo (4, 3-d)-pyrimidin-7-one)

Chemical formula: $C_{25}H_{36}N_6O_4S$

Molecular weight: 516.657 g/mol

Category: Impotence agents

Mechanism of action

Udenafil selectively inhibits phosphodiesterase type 5 (PDE5), thus inhibiting the degradation of cyclic guanosine monophosphate (cGMP) found in the smooth muscle of the corpus cavernosa and corpus spongiosum of the penis; inhibition of cGMP degradation results in prolonged muscle relaxation, vasodilation, and blood engorgement of the corpus cavernosa, and, so, prolonged penile erection. This responses is mediated by the release of nitric oxide (NO) from nerve terminals and endothelial cells, which stimulates the synthesis of cGMP in smooth muscle cells. The inhibition of phosphodiesterase type 5 (PDE5) by Udenafil enhances erectile function by increasing the amount of cGMP.

Erectile dysfunction (ED)

Erectile dysfunction (ED) is defined by the inability to achieve or maintain an erection sufficient for satisfactory sexual performance and is a common clinical entity that primarily affects men older than 40 years of age. ED is associated with various comorbidities or conditions, including advanced age, hypertension, hyperlipidemia, metabolic syndrome, lower urinary tract symptoms (LUTS) of benign prostatic hyperplasia (BPH), cardiovascular disease, central neuropathologic conditions, psychological factors, diabetes mellitus (DM), a result of radical prostatectomy, and the use of medications prescribed for the treatment of depression and hypertension.

Table 1: Chromatographic methods reported in the literature for the determination of Udenafil

Author Name/ Journal Name	Title Of The Journal	Chromatographic Conditions	Results	Reference
Sandesh and Patel, [5] Green Analytical Chemistry	A Green Perspective on Simultaneous HPLC and UV Spectrophotometric Estimation of Udenafil and Dapoxetine Hydrochloride in Pharmaceutical Formulations	Column: CHEMSIL ODS C18 Mobile phase: Mixture of Acetonitrile and Ammonium formate buffer having pH 5, adjusted with formic acid. Flow rate: 1 mL/min. Detection wavelength: 230 nm	Linearity: The absorbances have been found from 10 to 100 µg/mL Correlation coefficient (R2): 0.9991 LOD: 0.15 µg/ml LOQ: 0.45 µg/ml Robustness: Results showed that there was no statistically significant difference in the% RSD.	5
Natalija Nakov, Jelena Acevska, et, al., Chapter Metrics Overview	Green Strategies Toward Eco-Friendly HPLC Methods In Pharma Analysis	Column: monolithic columns. Mobile phase: Ethanol Flow rate: 1.2 mL/min. Detection wavelength: 210 nm	Ethanol, as the most extensively used green organic solvent, provides better method performances (Shorter runtime, better LOD, better LOQ , etc.) compared to conventional organic solvents (Acetonitrile and Methanol).	6
Abu Dayyih *et al*., Der Pharma Chemica	Reversed Phase HPLC for a Validation and Determination of Udenafil and Dapoxetine Simultaneously in Tablet Dosage Form in Jordanian Market	Column: Thermo Hypersil type-3-BDS-C18 Mobile phase: acetonitrile: 0.2% triethyl amine in H2O pH was adjusted to 4.4 with orthophosphoric acid as buffer solution in ratio of (75: 25) Flow rate: 1 mL/min. Detection wavelength: 246 nm	Linearity showed good correlation coefficient (R2 =0.999) for in given concentration range 0.30-6 µg/ml. LOD: 0.015 µg/ml LOQ: 0.035 µg/ml	7
Siddartha, and Sudheer European Journal Of Biomedical And Pharmaceutical Sciences	Analytical Method Development And Validation for the Estimation Of Udenafil in Bulk and Pharmaceutical Dosage Form by RP-HPLC	Column: Altima C18 column Mobile phase: mixture of buffers containing (Potassium dihydrogen orthophosphate, triethylamine, Ortho phosphoric acid solution and acetonitrile Flow rate: 1.0ml/min. Detection wavelength: 246 nm	Correlation coefficient R2: 0.999 Accuracy range: 99.48% and 101.54%. %RSD: values for both intraday and interday precision were less than 1%. LOD: 1.015µg/ml LOQ: 3.075µg/ml Retention time: 2.8 11 min	8
Siddartha, and Sudheer World Journal Of Pharmaceutical Sciences	Method Development and Method Validation of Udenafil in Bulk and Pharmaceutical Dosage Form by UV– Spectrophotometric Method	UV Spectrophotometric absorption in UV region using 0.1N HCl as solvent. Detection wavelength: 291nm	Linearity: 5-35µg/ml Correlation coefficient R2: 0.999 %RSD values for both intraday and interday precision were less than 2.0	9
Soo Kyung Bae, Min Jeong Kang et, al., Biomedical Chromatography	Simultaneous Determination of Udenafil and Its Active Metabolite, Da-8164, in Human Plasma and Urine Using Ultra-Performance Liquid Chromatography-Tandem Mass Spectrometry: Application to a Pharmacokinetic Study	Column: Acquity UPLC BEH C(18) column Mobile phase: Acetonitrile and containing 0.1% formic acid Flow rate: 0.4 mL/min Total run time was within 1 min	The assay was linear over a concentration range of 1-600 ng/mL with a lower limit of quantification of 1 ng/mL. The coefficient of variation of this assay precision was less than 13.7%, and the accuracy exceeded 92.0%.	10

Conclusion

According to the review's findings, there are numerous spectroscopic and chromatographic methods available for studying Impotence agents, such as Udenafil. It was discovered that Green solvents such as ethanol can be used as mobile phase which provides better method performances compared to conventional organic solvents such as acetonitrile and methanol. For the chromatographic approach, the flow rate and an appropriate retention period are recorded. Consequently, it has been determined that every procedure is simple, accurate, repeatable, economical, and exact. HPLC was the method most often employed because it provided the best possible sensitivity, reproducibility, dependability, and analysis time.

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