ISSN 0102-6593

caderno de farmácia

Órgão Oficial da Faculdade de Farmácia da Universidade Federal do Rio Grande do Sul
volume 26, Suplemento, 2010

DETERMINATION OF LODENAFIL CARBONATE IN TABLETS BY ULTRAVIOLET SPECTROPHOTOMETRY

Codevilla C.F.[1,*]; Castilhos T.S.[1]; Fröehlich, P.E.[1], Bergold, A.M.[1]

[1]Laboratório de Produção de Padrões Secundários (LAPPS), Faculdade de Farmácia, UFRGS.
***Doutoranda – Início: 2008/2**

Introduction: Erectile dysfunction (ED) is inability to achieve erection, an inconsistent ability to do so, or a tendency to sustain only brief erections.[1] ED is not a life-threatening disorder, but it influences the daily routine, social interactions, wellbeing and quality of life of the patient.[2] It may often constitute the first manifestation of important systemic or relational pathologies and it is considered a possible marker of clinically undiagnosed disease, thus representing the 'tip of the iceberg' of a systemic vascular disorder.[3] The phosphodiesterase type 5 (PDE5) inhibitors have revolutionized the way in which men with ED can be treated.[4] Lodenafil carbonate, is a new PDE5 inhibitor developed in Brazil, which is a dimer formed by two lodenafil molecules linked by a carbonate bridge.[5] No official or pharmacopoeial method have been reported for the assay of this drug in pharmaceutical formulation.
Objective: The aim of the present study was to develop and validate a spectrophotometric method for lodenafil carbonate quantitation in tablets.
Materials and Methods: An ultraviolet spectrophotometric method was elaborated using an UV-VIS Spectrophotometer Shimadzu (Shimadzu UV-1601PC). The solubility tests of lodenafil carbonate reference substance were performed in order to investigate the influences of solvents and, consequently, the influence of pH in the behavior of lodenafil carbonate. The stability of stock and dilute solutions were investigated in alkaline and acid media. A preliminary investigation was carried out to determine the method validation. The linearity of the method was developed and verified by ANOVA. In order to evaluate the presence of interferences in the sample known concentration of reference substance was added on the sample solution.
Results and Discussion: The best results were obtained when sodium hydroxide 0.1 M was used as solvent, while with the others (water, methanol and hydrochloric acid 0.1 M) lower efficiency and sensitivity were observed. Therefore, sodium hydroxide 0.1 M was chosen to prepare the stock solution. The stock solution was stable for 17 days when stored at 2 - 8 ºC. The ANOVA indicated that the analytical curve obtained shows no deviation from linearity, a significant linear regression ($p<0.05$) and the correlation coefficient was 0.9998. The lodenafil carbonate reference substance and pharmaceutical product solutions yielded similar spectra with maximum absorbance values at 292 and 212 nm. The results showed that the proposed method can be used for identification of lodenafil carbonate in tablets. Furthermore, the recovery test demonstrated that there wasn't contribution of excipients on the assay.
Conclusions: The proposed method can be used for the identification of lodenafil carbonate in pure form and in tablets. At this moment, we didn't finish the tablets quantitation but, after this step, the method will be validated according to International Conference on Harmonisation (ICH).

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Acknowldgements: Financial support from CNPq/Brazil.