ISSN 0102-6593

caderno de farmácia

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

DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR THE DETERMINATION OF TIZANIDINE HYDROCHLORIDE IN PHARMACEUTICAL FORMULATIONS

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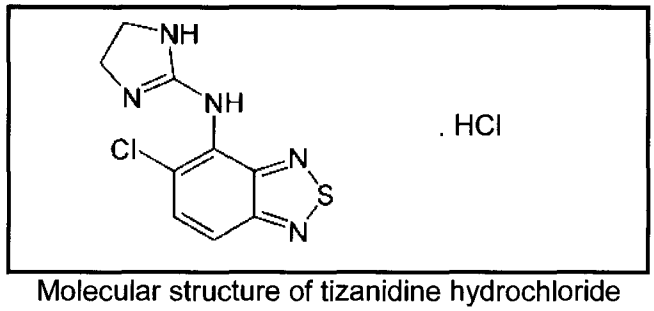
***Mestranda – Início: 2010/1**

Introduction: Spasm is a painful involuntary contraction of muscle that can cause involuntary movement, interfere with function, and cause distortion. It is a symptom of many muscular and other types of disorders and treatment should primarily be aimed at the underlying cause. Centrally acting muscle relaxants and benzodiazepines are used to treat muscle spasms such as splinting that occur in response to local trauma or musculoskeletal and joint disorders. Splinting is a reflex muscular spasm that produces muscular rigidity and acts as a protective mechanism to prevent movement and further damage of the affected part. Short courses of muscle relaxants may be considered in the management of acute low back pain [1, 2]. Tizanidine [5-chloro-4-(2-imidazolin-2-ylamino)-2,1,3-benzothiadiazol], a central alpha-2 adrenoceptor agonist, is a myotonolytic agent used in the treatment of spasticity in patients with cerebral or spinal injury. Clinical trials with tizanidine when administered alone have shown that it is safe and effective for spasticity control [3]. It was developed by Novartis Company and marketed as Sirdalud® in the pharmaceutical form of tablets and in dosage of 2mg.
Objective: The aim of the present work will be to develop and validate methods to determinate tizanidine hydrochloride to be used as tools to its quality control. The developed methods will be: non-aqueous titration and liquid chromatography (LC).
Materials and Methods: In the selection of titration conditions the quantity of chemical substance that will be used, must be determined. For the titration 0,1 M perchloric acid will be used. For the LC conditions, factors like selection of mobile phase, flow rate and pH, columns of different stationary phases, optimal wavelength for detection, injection volume and analysis temperature will be studied. All proposed methodologies will be validated and comparative study will be performed. Up till now, samples of pharmaceutical formulation of Sirdalud® and the tizanidine hydrochloride material were purchased.
Results and Discussion: A few tests, solubility, loss on drying, residue on ignition, pH and identification of chloride and primary aromatic amine, after hydrolysis, were already performed.



Molecular structure of tizanidine hydrochloride

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