EVALUATION OF ACUTE TOXICITY AND ANXIOLYTIC EFFECT OF NANOCAPSULES CONTAINING DULOXETINE HYCLORIDATE

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INTRODUCTION: Duloxetine Hydrochloride is approved by Food and Drug Administration (FDA) for generalized anxiety disorder and other pathologies. However, adverse effects and degradation in acidic environments are presented. Nanotechnology is used to optimize the therapeutic effect of drugs and nanocapsules increases the stability of active ingredients, controlling drug release, improving bioavailability and reducing adverse effects. OBJECTIVE: the objective of this work was to evaluate the acute toxicity and anxiolytic effect of nanocapsules containing duloxetine hydrochloride in BALB/C mice. MATERIALS AND METHODS: The formulations were obtained by nanoprecipitation method and characterized in terms of particle size, polydispersity index, zeta potential, pH and content. Nanocapsules are composed by core-forming oil (medium-chain triglycerides), poly-(ε-caprolactone) polymer, surfactants (egg lecithin and polysorbate 80) and the drug duloxetine hydrochloride (1mg/mL). To evaluate acute toxicity, 1mg/mL of the formulations was orally administered and the animals were observed and weighed for 14 days. The anxiolytic effect was evaluated in the elevated plus maze and open field tests in mice. RESULTS AND CONCLUSION: The nanocapsules presented particle size of 212.72 ± 4.18 nm, polydispersity index 0.12 ± 0.06, zeta potential -20.59 ± 10.12 mV, pH 5.08 ± 1.19 content of 98 .27 ± % (0.98 mg/mL). Nanocapsules showed no signs of toxicity and no statistically significant differences in weight gain and feed consumption compared to the control. Previous results from the anxiolytic evaluation effect indicates that the nanocapsule containing duloxetine hydrochloride has a tendency to increase the anxiolytic effect compared to the free drug. No difference in relation to the control in spontaneous locomotor activity was

observed. Therefore, more studies are being carried out in order to prove the potential anxiolytic effect of the nanostructure containing duloxetine hydrochloride.

Keywords: duloxetine hydrochloride, nanocapsule, toxicity, anxiety