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Development and validation of a novel analytical method for quantification of a new chromene-based molecule using RP-HPLC

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Synthetic chromene-based molecules have proven their potential for cancer treatment, acting on several molecular targets involved in cancer progression. (1) The broad pharmacological properties of chromene derivatives are an inspiration for the design of novel drug candidates. However, some physical-chemical characteristics of chromenes such as limited solubility in an aqueous environment suggest their entrapment into polymeric delivery systems based on poly(lactide-co-glycolide) (PLGA) polymer. The development of nanotechnology-based delivery systems requires novel analytical approaches to assess loading and release capacity. Additionally, we also see great demand for analytical methods that can accurately quantify this compound. This study aimed to develop and validate a new method for quantification of a novel chromene-based molecule in nanoparticulate systems by reverse phase high-performance liquid chromatography (RP-HPLC) coupled to ultraviolet detection (HPLC-UV). The proposed method was validated following the guidelines of the International Conference on Harmonization (ICH) Q2 (R1) concerning linearity, specificity, accuracy, precision, stability, and method applicability. Chromatographic separation was performed using a C18 column (Gemini 250 \times 4.6 mm, 5 μ m) with the mobile phase composed of 0.5 % (v/v) acetic acid (HAc) and acetonitrile (ACN) (55:45%) on isocratic mode at a temperature of 35°C and a flow rate of 1 mL/min. All the validation parameters were within the acceptable limits. The developed method was successfully used for the first time to quantify the chromene derivative content in poly(lactide-co-glycolide)-based nanoparticles, with acceptable analytical performance and can be used in further studies applied to anticancer therapy.

Palavras-chave: HPLC. Method validation. Chromene derivatives.

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Referências:

1 COSTA, M. *et al.* Biological importance of structurally diversified chromenes. **European Journal of Medicinal Chemistry**, v 123, p. 487-507, 2016.