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### Recent advances in the study of the inclusion complex darunavir: $\beta$ -cyclodextrin by LC-MS

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**D**arunavir is a protease inhibitor used in the treatment of HIV infection. It is a pillar of therapy cocktail for patients with the virus. This work proposed a LC-MS method indicative of stability for the determination of darunavir in the complex darunavir: $\beta$ -cyclodextrin, a recent advance for the use of antiretroviral. The method was completely validated according to the International Summit on Harmonization guidelines, showing accuracy, precision, selectivity, robustness and linearity. The separation was achieved on a 250 mm  $\times$  4.6 mm, 5.0  $\mu$ m particle size CN Luna column with water + 0.1% glacial acetic acid : acetonitrile + 0.1% glacial acetic acid, 60:40 (v/v) at phase at a flow rate of 1.0 mL min<sup>-1</sup>. UV detection was performed at 268 nm at ambient room temperature (25°C). Mass spectral analyses were performed with ESI ion source and ion trap mass analyser. The method was linear over the concentration range of 10-60  $\mu$ g mL<sup>-1</sup> with correlation coefficients 1.000 and limits of detection and quantification of 1.13 and 3.43  $\mu$ g mL<sup>-1</sup>, respectively. The drug was subjected to acid, basic, oxidative, neutral degradation and photolysis. Degradation products were identified by LC-MS and LC-MS/MS and they showed no interfere in the method of darunavir, therefore the method can be regarded as indicative of stability. The validated method is very useful to the routine quality control for quantification of darunavir in inclusion complex darunavir: $\beta$ -cyclodextrin.

#### Biography

Ana Carolina Kogawa graduated in Pharmacy-Biochemistry (2008), Master (2012) and PhD in Pharmaceutical Sciences (2015) all from the "Universidade Estadual Paulista - UNESP". She has experience in managing people and projects, coordinating activities in the junior company of the university (All Pharma Jr.), teaching experience gained from ministry personnel training in the All Pharma Jr. and JP Pharmaceutical Industry company. She has experience in industrial activity in Drugs and Medicines, with emphasis on Quality Control. Currently she conducts research with the drug rifaximin for the development of its Postdoctoral research at the Faculty of Pharmaceutical Sciences of UNESP.

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