ABSTRACT

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Title of thesis: Determination of related substances in the dosage forms based on cyclosporine by HPLC with nitrogen specific chemiluminescence detection.

Development of an HPLC method with chemiluminescent detection specific for nitrogen for related substances determination in cyclosporine final dosage forms is described in this work. The method is capable to determine cyclosporine impurities originated from cyclosporine substance and relevant degradation products except isocyclosporines.

The method utilizes the stationary phase Zorbax SB-C18, particle size 1.8 µm, 150x2.1 mm and gradient elution at flow rate 0.15 $ml.min^{-1}$ at column temperature 100°C. Mobile phases are Acetone: TBME: water: TFA (30: 5.5: 64.5: 0.01) and Acetone: TBME: water: TFA (49: 5.5: 45.5: 0.01).

The work includes the verification of method validability in terms of specificity, linearity, limit of quantittion, accuracy, precision and robustness. The method can be used for determination of cyclosporine impurities in final dosage forms in pharmacetical QC laboratories.

Keywords: cyclosporine. Cyclosporine A. cyclosporine related substances. cyclosporine degradation compounds. chemiluminescent detector. nitrogen detector.