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A Simple and Sensitive HPLC Method For Determination of Tacrolimus in Pharmaceutical Dosage Forms

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Tacrolimus (TCL) is an immunosuppressive drug commonly used in organ transplant patient rejection.[1] A simple and sensitive RP–HPLC method with UV detection was developed for determination of tacrolimus in pharmaceuticals. The separation was performed on a Watters ODS 2 column (125 mm x 4.0 mm, 5µm) with a mobile phase consisted of acetonitrile and water acidified to pH of 4.0, 45:55 (*V/V*). The flow rate was set at 1 mL min^{-1} and UV detection was performed at 210 nm. The method was validated by determination of system suitability, specificity, linearity, precision, accuracy, limit of detection and limit of quantitation and robustness, following the ICH Q2(R1) guidelines.[2] The advantages of this method were: simple sample preparation, good precision (RSD < 2%) and high recovery (> 99%). Linearity was studied in the range of 0.0397 – 0.318 mg mL^{-1}. The limit of detection was 8.1 µg mL^{-1}, while limit of quantitation was 24.6 µg mL^{-1}. The limit of detection was compared with the one determined by DPV – Differential Pulse Voltammetry for the electrochemical nanosensor for the TCL. The main peak was obtained at 2.2 V for 0.0025M TCL. The method could be applied for routine quality control of pharmaceuticals and for evaluation of potentially counterfeit capsules containing TCL.

Keywords: Tacrolimus; High performance liquid chromatography; Immunosuppressive drugs

References

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