Original article

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VALIDATION OF HPLC METHOD FOR THE DETERMINATION OF MYCOPHENOLIC ACID IN HUMAN PLASMA OBTAINED FROM RENAL TRANSPLANT RECIPIENTS

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A simple, fast and sensitive HPLC method combined with protein precipitation has been developed and validated for the determination of mycophenolic acid in human plasma, obtained from renal transplant recipients. For the analysis to be performed, the C18 Bakerbond-BDC analytical column (250 mm x 4.6 mm i.d., particle size 5 μm) was used. For chromatographic separation the optimal conditions were established with the mobile phase acetonitrile - 10 mM phosphate buffer, pH 2.5 (50:50, v/v) at the flow rate of 1.0 mL/min, temperature 30°C, and detection at 215 nm. Chromatographic run time was about 6 minutes. Precipitation of plasma proteins was performed by the addition of 0.3% trifluoroacetic acid in acetonitrile (v/v). The HPLC method combined with protein precipitation was subjected to validation. Linearity was observed over the concentration range of 0.2-100 μg/mL for mycophenolic acid with correlation coefficient 0.9995. Moreover, a good intra-day and inter-day precision was confirmed, with relative standard deviation below 8.64%, while accuracy ranged from 89.31% to 107.67% for mycophenolic acid. Finally, the method was successfully applied in the analysis of plasma samples obtained from renal transplant recipients in polytherapy. *Acta Medica Medianae 2016;55(4):28-36.*

Key words: *mycophenolic acid, human plasma, protein precipitation, high-performance liquid chromatography*