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Development and Validation of Stability Indicating Lc- Pda Method for Mycophenolate Mofetil (Mmf) in Presence of its Impurities and Major Degradation Product Mycophenolic Acid (Mpa) Using Factorial Design Tool and Use of Mass Spectroscopy

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Factorial design tool was applied for development of isocratic reversed-phase stability indicating HPLC method for the analysis of Mycophenolate mofetil (MMF), its degradation products Mycophenolic acid (MPA) and degradation products (DP3). Separation was achieved on a Symmetry C18 (250 mm × 4.6 mm, 5.0 µ) column using a Methanol: acetate buffer (75:25 v/v), pH 6.0 (adjusted with acetic acid), at 0.5 ml flow rate, column maintained at 55 ^{0}C and data was integrated at 251 nm. MMF was subjected to hydrolysis, oxidation, heat degradation, etc. under all these conditions degraded products were well separated. The method validation characteristics included accuracy, precision, linearity, range, specificity, LOD and LOQ. Robustness testing was conducted to evaluate the effect of minor changes to the chromatographic conditions and to establish appropriate system suitability parameters. The proposed method was used to investigate kinetics of acid, alkali hydrolysis and oxidation process. Major degradation product MPA and DP3 were isolated and quantitated. Characterization of MPA by NMR and LC-MS/MS and other degraded products by LC-MS/MS was attempted successfully. The method was used successfully for the quality assessment of three MMF drug products and its acid, alkali and oxidative degradation kinetics study. A simple and efficient stability indicating reverse-phase HPLC method was developed and was found to be accurate, precise and linear across the analytical range and is reported for the first time. The method is simple, fast, sensitive and specific for the determination and quantification of MMF, MPA and DP3.