16th International Conference and Exhibition on

Pharmaceutical Formulations

July 26-27, 2018 | Rome, Italy

HPTLC-densitometric method development and validation for simultaneous determination of lamivudine and efavirenz in fixed dose combinations

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In this study an HPTLC densitometric method was developed for the simultaneous determination of lamivudine and efavirenz in pharmaceutical dosage forms which are used widely as first line HIV/AIDS treatment. Chromatographic separation of the drugs was performed on precoated silica gel 60F 254 (0.2 mm thickness) plates using chloroform: methanol (9:1, v/v) as a mobile phase. A TLC scanner set at 255 nm was used for the direct evaluation of the chromatogram in reflectance absorbance mode. The two drugs were satisfactorily resolved with Rf values of 0.12 ± 0.03 , and 0.76 ± 0.04 for lamivudine and efavirenz respectively. Calibration curves were in the range 100-500 ng/band for lamivudine and from 300 - 1500 ng/band for efavirenz Correlation coefficients (r) values were 0.9988 for lamivudine and 0.9985 for efavirenz. A low relative standard deviation (< 2%) was found for both precision and robustness study showing that the proposed method was precise and robust. The method had an accuracy of 99.34% and 99.37%; and percentage assay of 99.52% and 100.21% for lamivudine and efavirenz respectively. Method had the potential to determine these drugs simultaneously from dosage forms without any interference.

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