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Method development and validation of the assay and dissolution of a fixed dose combination of tenofovir and efavirenz tablet

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A reverse phase-high performance liquid chromatographic method was developed and validated for the simultaneous determination of tenofovir disoproxil fumarate and efavirenz in tenofovir and efavirenz finished formulation product. The method was developed by altering various organic solvents such as acetonitrile and methanol, column, detection, flow rate and temperature. An isocratic elution mode with a mixture of acetonitrile and water in the ratio of (55:45 % v/v) was selected for the mobile phase with a C18 (4.6 mm x 250 mm x 5□m) column as stationary phase for simultaneous separation of tenofovir disoproxil fumarate and efavirenz. The separation was achieved at a flow rate of 1 mL/min and detection wavelength of 252 nm at room temperature. Further, different dissolution media were investigated for optimal release of tenofovir disoproxil fumarate and efavirenz from lamivudine, tenofovir and efavirenz tablets. The optimization of dissolution medium was preceded by establishment of the sink concentration for efavirenz (which is class-II drug) which was found at 0.5% sodium dodecyl sulphate in water with a release of more than 75% of each of the three active pharmaceutical ingredients at 37°C with a paddle method, 75 rpm at 45 min. The analytical method was validated and the linear range was found in the concentration range of 0.05 to 0.12 mg/mL of tenofovir disoproxil fumarate and efavirenz with regression coefficient (r2) of 0.9984 which met the acceptance criteria of r2 equal or greater than 0.98. The % rsd for the intra-day precision were 1.23% and 1.46% for tenofovir disoproxil fumarate and efavirenz respectively. The % rsd for the inter-day precision were 1.99% and 1.67% for tenofovir disoproxil fumarate and efavirenz respectively. The test method had an acceptable level of accuracy for the assay of tenofovir disoproxil fumarate and efavirenz in tenofovir and efavirenz tablets from 50 % to 120 % of test concentration with % rsd less than 2% for all three active pharmaceutical ingredients. The test solution remained stable when stored at 4°C for 72 hours. The method was robust as it remained largely unaffected by small variations in temperature and mobile phase. All of these assessed parameters complied with the acceptance criteria hence indicated the usefulness of the reverse phase-high performance liquid chromatographic method for determination of assay and dissolution release testing for finished formulation product which contain tenofovir disoproxil fumarate and efavirenz active substances.

Markers as prognostic and predictive tools in cancer: where are we now?

Dharma Teja

Despite different available methods for cancer screening and their proven benefits, morbidity, and mortality of this malignancy are still high, partly due to low compliance with screening. Minimally invasive tests based on the analysis of blood specimens may overcome this problem. The purpose of this review as to give an overview of published studies on tumor markers aimed at the early detection of cancer and to summarize their performance characteristics. Only studies more than 20 cases and more than 20 controls were included. Information on the markers under study, on the underlying study populations, and on performance characteristics was extracted. Special attention was given to performance characteristics by tumor stage. Overall, 93 studies evaluating 70 different markers were included. Most studies were done on protein markers, but DNA markers and RNA markers were also investigated. Performance characteristics varied widely between different markers, but also between different studies using the same marker. Promising results were reported for some novel assays, e.g., assays based on SELDI-TOF MS or MALDI-TOF MS, for some proteins (e.g., soluble CD26 and bone sialoprotein) and also for some genetic assays (e.g., L6 mRNA), but evidence thus far is restricted to single studies with limited sample size and without further external validation. Larger prospective studies using study populations representing a screening population are needed to verify promising results. In addition, future studies should pay increased attention to the potential of detecting precursor lesion.