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A rapid stability-indicating, fused-core HPLC method for simultaneous determination of beta-artemether and lumefantrine in anti-malarial fixed dose combination products

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Artemisinin-based FDC products are recommended by WHO as first-line treatment. However, the current artemisinin FDC products, like β-artemether and lumefantrine, are inherently unstable and require controlled distribution and storage conditions. Moreover, quality control is hampered by lack of suitable analytical methods. Thus, there is a need for a rapid and simple stability-indicating method for the simultaneous assay of β-artemether and lumefantrine. Three reversed-phase fused-core halo HPLC columns (RP-Amide, C18 and Phenyl-hexyl), all thermostated at 30°C, were evaluated. β-artemether and lumefantrine (including stressed), and reference-related impurities were injected and chromatographic parameters were assessed. Optimal chromatographic parameters were obtained using RP-Amide column and isocratic mobile phase composed of acetonitrile and 1 mM phosphate buffer pH 3.0 (52:48; V/V) at flow of 1.0 ml/min and 3 µl injection volume. Quantification was performed at 210 nm and 335 nm for β-artemether and lumefantrine, respectively. Both β-artemether and lumefantrine were separated from each other, and from the specified and unspecified related impurities including degradants. A complete chromatographic run only took four minutes. Evaluation of the method, including Plackett-Burman robustness verification within analytical QbD-principles, and real-life samples showed the method is suitable for quantitative assay purposes of both active pharmaceutical ingredients, with a mean recovery (±RSD) of 99.7% ±0.7%) for β-artemether and 99.7% (±0.6%) for lumefantrine. A rapid, robust, precise and accurate stability-indicating, quantitative fused-core isocratic HPLC method was developed for simultaneous assay of β-artemether and lumefantrine. This method can be applied in the routine regulatory quality control of FDC products.

Biography

Sultan Suleman is at his final year of his Ph.D. study at University of Ghent, Belgium in Pharmaceutical Sciences. He was head of School of Pharmacy of Jimma University, Jimma, Ethiopia and now is the founder and director of Laboratory of Drug Quality at Jimma University, Jimma, Ethiopia. He has published more than 18 papers in reputed journals and has been serving as assistant professor at School of Pharmacy of Jimma University while studying his Ph.D. on sandwich basis.

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