Development of Analytical Method and Forced Degradation Study of Emtricitabine and Tenofovir Alafenamide using RP-HPLC Technique

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Abstract

A reverse phase high performance liquid chromatographic (RP-HPLC) method is presented for the quantification of Emtricitabine (EMT) and Tenofovir Alafenamide (TEN) in combination. Separation was achieved under optimized chromatographic condition on an Inertsil C18, 250 x 4.6 mm, 5μm column. Various composition of mobile phase was tried. Separation of EMT and TEN was started with HPLC grade Acetonitrile: Water, Methanol: Water and Methanol: Buffer and Methanol finally using solvent system of Buffer (pH 3.5) and Methanol in ratio of (30:70) and flow rate adjust at 1.0 ml/min was used as solvent system, The detection was carried out at 262nm nm using Shimazdu UV-visible detector SPD-20AT. The mobile phase run time for the developed analytical method was 10 minutes. The standard curve was found linear in the concentration range of 20-60 μg/ ml (r2- 0.9994) and 2.5-7.5 μg/ ml (r2-0.9992) for EMT and TEN respectively. forced degradation study of the EMT and TEN was also carried out at various conditions. The proposed developed RP-HPLC method was validated statistically and the values were found to be within the acceptable limits. In conclusion, the developed RP-HPLC method was found to be simple, specific, and rugged for simultaneous estimation of EMT and TEN. Validation results of method was found within the acceptable limits. Hence it can be used for analysis of EMT and TEN.

Biography:

Khushboo M. Patel has completed her post graduate studies in the area of Quality Assurance at the age of 25 years from L. J. Institute of Pharmacy, Gujarat Technological University, Ahmedabad, Gujarat, India and continuing Ph.D from Faculty of Pharmacy, Sankalchand Patel University, Visnagar, Gujarat, India. She is currently founder of Aveon Pharmaceutical Distributor, Managing Director of Homway Infrastructure LLP, Director of Ale Distributors Pvt. Ltd. Managing Director of Aveon Pharmacy. She managing all the Pharmaceutical Companies and more than 500 employees works under her training. She is also managing Homway Infrastructure LLP across India, a company which refurbishes and restores Heritage Sites across India (Projects under Government of India). She recently received an award for Women Empowerment and achiever as an entrepreneur from our honorable Chief Minister of Gujarat - Shree Vijay Rupani.

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