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A new validated stability-indicating RP-HPLC method for simultaneous quantification of dolutegravir and lamivudine in bulk and pharmaceutical dosage form

Khaleel Noorbasha^{1*} and Sharmila Nurbhasa²

Abstract

Background: A fresh selective, rapid, accurate, precise and RP-HPLC stability-indicating method was developed and validated for the quantitative simultaneous determination of dolutegravir and lamivudine in the bulk as well as pharmaceutical dosage form. A chromatographic separation was done by using Inertsil ODS 3V (250 × 4.6 mm, 5 μm) column and mobile phase composed of phosphate buffer, pH 3.0:acetonitrile:methanol (50:20:30% w/w/v) with flow rate of 1.0 mL/min, and the detection of eluents was carried out at a wavelength of 257 nm utilizing a PDA detector. The drugs, dolutegravir and lamivudine, were subjected to varied conditions like base hydrolysis, acid hydrolysis, oxidation, thermal, photochemical and UV. The suggested method was analysed statistically and validated to fulfil requirements of International Conference on Harmonisation (ICH) and the validation covered accuracy, precision, linearity, limit of detection (LOD), limit of quantification (LOQ), robustness, ruggedness and specificity.

Results: The retention time of dolutegravir and lamivudine were observed to be 6.36 and 2.16 min, respectively. The method was found to be linear within the range of 14.98 to 91.25 μg/mL for lamivudine and 2.54 to 15.35 μg/mL for dolutegravir. The percentage recoveries (accuracy) for dolutegravir and lamivudine were in the range of 98.35 to 102.14% and 98.01 to 101.5%. The computed relative variance (%RSD) was within the suitable criterion of less than 2.0.

Conclusion: The suggested method was set to be precise as well as stability-indicating since no interfering degradant peaks and excipients were evident. All the peaks of degradation were successfully resolved by the use of the developed analytical method with altered retention times. Results obtained were analysed statistically and found to be acceptable in line with the ICH guidelines. Hence, such method is often employed successfully for routine analysis of active analytes in the bulk as well as pharmaceutical dosage form. It is going to be extended to review for its estimation in plasma and other biological fluids and may even be employed for quality control stability sample estimation and in cleaning method analysis during cleaning validation.

Keywords: Dolutegravir, Lamivudine, RP-HPLC, Acetonitrile, Methanol, Buffer

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