Latin American Journal of Pharmacy
(formerly *Acta Farmacéutica Bonaerense*)
Lat. Am. J. Pharm. **43** (9): 1903-9 (2024)

Received: February 26, 2024
Accepted: April 29, 2024

Analytical Method Development and Validation for the Simultaneous Estimation of Dolutegravir and Lamivudine by RP-HPLC in Bulk and Tablet Dosage Form

Shankar S. YELMAME [1] * & Sunil V. AMRUTKAR [2]

[1] *Department of Pharmaceutical Chemistry, SNJB's Shriman Sureshdada Jain College of Pharmacy, Jain Gurukul, Neminagar, Chandwad, Dist- Nashik, Maharashtra, India 423101.*

[2] *Department of Pharmaceutical Chemistry, Gokhale Education Society's, Sir Dr. M. S. Gosavi College of Pharmaceutical Education and Research Centre, Nashik, Maharashtra, India 422005.*

SUMMARY. A simple, rapid and precise high performance liquid chromatographic method was developed and validated for simultaneous estimation of Dolutegravir and Lamivudine in their tablet dosage form. A Phenomenex ODS-3 column (250 mm × 4.6 mm, 5 µm) was used to establish the technique. The mobile phase used was acetonitrile: 0.1% OPA in water (40:60% v/v) at a flow rate of 1 mL/min with isocratic elution. The chromatographic system was injected with 20 µL of material. Using a UV detector, the two eluted chemicals were found with a wavelength of 269 nm. At 40 °C, the column temperature was kept constant. Dolutegravir and lamivudine were shown to have retention durations of 9.8 min and 1.8 min, respectively. For dolutegravir and lamivudine, the linearity range was 2.5 to 7.5 µg/mL and 15 to 45 µg/mL, respectively, with correlation coefficients of 0.9998 and 0.9999. Dolutegravir and Lamivudine were shown to have recovery percentages of 99.15% and 99.67%, respectively. LOD and LOQ values for dolutegravir and lamivudine were determined to be 0.08 µg and 0.37 µg, respectively. The present method was simple, rapid, precise and accurate.

RESUMEN. Se desarrolló y validó un método de cromatografía líquida de alto rendimiento simple, rápido y preciso para la estimación simultánea de dolutegravir y lamivudina en su forma farmacéutica en tabletas. Se utilizó la columna Phenomenex ODS-3 (250 mm × de agua (40:60% v/v) a un caudal de 1 mL/min con elución isocrática. Al sistema cromatográfico se le inyectaron 20 µL de material. Utilizando un detector UV, se encontraron las dos sustancias químicas eluidas con una longitud de onda de 269 nm. A 40 °C, la temperatura de la columna se mantuvo constante. Se demostró que dolutegravir y lamivudina tenían duraciones de retención de 9,8 min y 1,8 min, respectivamente. Para dolutegravir y lamivudina, el rango de linealidad fue de 2,5 a 7,5 µg/mL y de 15 a 45 µg/mL, respectivamente, con coeficientes de correlación de 0,9998 y 0,9999. Se demostró que dolutegravir y lamivudina tenían porcentajes de recuperación del 99,15% y 99,67%, respectivamente. Se determinó que los valores LOD y LOQ para dolutegravir y lamivudina eran 0,08 µg y 0,37 µg, respectivamente. El método actual fue simple, rápido, preciso y exacto.

KEYWORDS: dolutegravir, lamivudine, method development, RP-HPLC, simultaneous, validation.

* Author to whom correspondence should be addressed. E-mail: shankar.yelmame@gmail.com

ISSN 0326 2383 (printed ed.)
ISSN 2362-3853 (on line ed.)