IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 1, July 2024

Analytical Method Development and Validation of Antidiabetic Drugs by using RP-HPLC

Miss. Shruti Pradip Dhanmane, R. R. Pagore, A. A. Gawai, K. R. Biyani
Anuradha College of Pharmacy, Chikhali, Buldana, Maharashtra, India

Abstract: *This study presents the development and validation of a reverse-phase high-performance liquid chromatography (RP-HPLC) method for the quantitative analysis of the antidiabetic drug saxagliptin monohydrate. Utilizing an HPLC system equipped with a C18 column (4.6 x 250 mm, 5 µm), the method employed a mobile phase of acetonitrile, methanol, and water in a 40:10:50 ratio, adjusted to pH 3.5 with o-phosphoric acid. The detection wavelength was set at 223 nm, with a flow rate of 0.7 ml/min and a sample injection volume of 20 µl. The retention time for saxagliptin monohydrate was observed at 3.98 minutes, and the method demonstrated excellent linearity over a concentration range of 10-50 µg/ml with a regression coefficient (R^2) of 0.999. Validation parameters, including accuracy, precision, linearity, ruggedness, and limits of detection (LOD) and quantitation (LOQ), confirmed the method's reliability and robustness. The LOD and LOQ were determined to be 0.5815 µg/ml and 1.7622 µg/ml, respectively. This RP-HPLC method proved to be effective for the routine analysis of saxagliptin monohydrate in pharmaceutical formulations, providing a specific, sensitive, and reproducible analytical tool.*

Keywords: RP-HPLC, saxagliptin monohydrate, method development, validation, antidiabetic drug, linearity, precision, accuracy

DOI: 10.48175/568
ISSN 2581-9429 IJARSCT