Journal of Innovations in Pharmaceutical and Biological Sciences (JIPBS)
ISSN: 2349-2759
Available online at www.jipbs.com

Research article

Validation of stability indicating high performance liquid chromatographic method for simultaneous determination of assay of Linagliptin and Metformin drugs in the pharmaceuticals tablet formulations using bupropion as a common internal standard

Shaikh Javed Shaikh Afzal[1*], Mohamad Asif[2], Pathan Mohd Arif Ali Khan[2]

[1]Faculty of Science, Pacific Academy of Higher Education and Research University, Udaipur-313003, India.
[2]Maulana Azad College of Arts, Science and Commerce, Dr. Rafiq Zakaria Campus, Rauza Bagh, Aurangabad – 431001, India.

Key words: Linagliptin, Metformin Hydrochloride, Bupropion Hydrochloride, High Performance Liquid Chromatographic, Force degradation studies, Assay.

***Corresponding Author: Shaikh Javed Shaikh Afzal,** Faculty of Science, Pacific Academy of Higher Education and Research University, Udaipur-313003.

Abstract

Linagliptin is a DPP-4 inhibitor developed by Boehringer Ingelheim and used for the treatment of type II diabetes. Metformin is a biguanide antihyperglycemic agent used for treating non-insulin-dependent diabetes mellitus (NIDDM).Validation of stability indicating Simple, Specific, Precise, Accurate, Linear, Rugged, Robust High Performance Liquid Chromatographic method of analysis for simultaneous determination of assay of Linagliptin and Metformin drugs in the pharmaceuticals Tablet formulations using Bupropion as a common internal standard was performed. The assay was accomplished using a mixture of Ammonium phosphate buffer (pH 3.00), and methanol in the volume ratio of 40:60 v/v as mobile phase on an Inertsil ODS2, 150 mm x 4.6mm, 5µ as chromatographic column at a flow rate 0.800 mLmin-1and with a uv detector at a wavelength 233nm. The temperature of auto injector and column oven was 10^0C and 30^0Creceptively. The Injection volume of HPLC system kept as 30µL.linearity of the analytical method was evoluted at concentration range of 0.5123 µg/ml to 11.2299 µg/ml for Linagliptin and 159.6713 µg/ml to 3500.0690 µg/ml for Metformin respectively with Correlation coefficient (r) value more than 0.999.The LOD and LOQ was 0.1036µg/mL and 0.3140 µg/mL for Linagliptin and 46.4871µg/mL and 140.8700µg/mL for Metformin respectively. The retention time found to be 3.35 min for Linagliptin, 7.80min for Metformin and 3.00 min for Internal standard. Specificity, Method Precision, System Precision, Ruggedness, Robustness, Recovery, Stability of analytical solution, Filter paper selection study, Stress testing (Force Degradation) at various conditions were performed as per the ICH (Q2) recommendations. All the results were found within acceptance criteria.