Dina Abushanab et al., Pharm Anal Acta 2015, 6:1
http://dx.doi.org/10.4172/2153-2435.S1.025

OMICS International
Pharmaceuticalconferences.com

5th International Conference and Exhibition on

Pharmaceutics & Novel Drug Delivery Systems

March 16-18, 2015 Crowne Plaza, Dubai, UAE

Development and validation of stability and bioavailability indicating LC-MS/MS method for the determination of Letrozole in biological fluids

Dina Abushanab, Fatima Hazi, Nurhan El Shafey, Rym Skanji, Fathy Atia, Saeed Al Meer and **Husam M Younes**
Qatar University, Qatar

Purpose: Letrozole (LZ) is a non-steroidal aromatase inhibitor that is used inthe treatment of breast cancer. Our lab is currently conducting *in vitro* and *in vivo* studies on a newly developed dosage formof LZ, which requires the development of a highly sensitive method of analysis. The main objective of this study therefore, was to develop and validate a simple, rapid, stability and bioavailability indicating liquid chromatography-mass spectrometry (LC-MS/MS) method for the determination of LZ in biological fluids.

Methods: Following liquid phase extraction, the analysis was performed using Agilent 1290 rapid resolution LC-system equipped with zobrax eclipse XDB C18 column (4 µm, 4.6 × 200 mm)maintained at 30oC. The mobile phase consisted of 0.1% Acetic Acid in water as solvent A and acetonitrile solvent B (30/70) using isocratic program with flow rate 1.25 ml/min. The injection volume was 10 µL. Progesterone (PG) was used as an internal standard. All chromatograms were recorded and analyzed on Agilent Mass Hunter software. MS analysis was performed by multiple reaction monitoring (MRM) mode using 6460 triple quadrupole mass spectrometer (Agilent) equipped with a Jet stream electrospray source. The method was fully validated using international on harmonization conference (ICH) and FDA guidelines.

Results: The retention timeswere 0.89and 2.35 min for LZ and PG respectively. The method was specific and sensitive to LZ and was found linear over the concentration range of 25pg/ml- 200 ng/ml (R2 = 0.999). The limit of detection and the limit of quantitation were found to be 8.7 and 17.5 nM, respectively. The inter-day and intra-day precisions (% RSD) were within acceptable limits. All other validation parameters were in the acceptable range within ICH guidelines.

Conclusion: The proposed LC/MS/MS method is simple, rapid, accurate, and can be successfully used for the analysis of LZ in blood and urine for assessment of its bioavailability and drug monitoring.

Acknowledgement: This workwas made possible by a UREP award [UREP 15 - 058 - 3 - 014] from the Qatar National Research Fund (a member of The Qatar Foundation) awarded to H. Younes. The statements made herein are solely the responsibility of the author[s]. Nurhan El Shafey, Fatima Hazi and Dina Abushanab were financially supported by UREP 15th cycle of funding.

da091121@student.qu.edu.qa
ne092822@student.qu.edu.qa
fh1000913@student.qu.edu.qa