DETERMINATION OF OLANZAPINE IN PHARMACEUTICAL FORMULATIONS BY LC-MS METHOD

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Olanzapine which is named as 2-methyl-4-4-(4-methyl-1-piperazynyl)-10H-thio (2,3-b)(1,5) benzodiazepine is used as a pharmaceutical formulation since 1985¹. Olanzapine is an atypical antipsycotic drug that has a great affinity to dopamine (D₁, D₂, D₃, D₄), serotonine (5HT-2A, 5HT-2C, 5HT3, 5HT6), muskarinic (M1, M5) histamine H1 and 1 adrenenjenik receptors². By this way it can differentiated from the unselective typical antipsycotics which block the both stratial and limbic neurons and cause adverse effects¹,².

In this study, it is aimed to develop and validate an accurate, precise, sensitive LC-MS method to determine olanzapine in pharmaceutical formulations. In order to carry out this study, method parameters were optimized to be 1 mL/min flow rate, 25°C column temperature, 0.1% TFA-acetonitrile (20:80 v/v) mobile phase, positive ion mode with 313 m/z ratio, 100 V fragmentor voltage, 5µA corona current and Agilent C₁₈ column (5 µm, 150 x 4.6 mm).

The proposed method were validated with respect to the ICH guideline. Method was linear between 2-300 ng/mL precision and accuracy of the method was lower than 7.55% and 7.59%, respectively. Valsartan was selected as internal standard (IS). LOQ and LOD values was 2 ng/mL and s 0.8 ng/mL, respectively.

Developed and validated LC-MS method was applied onto 5 different pharmaceutical formulations which were purchased from local pharmacy store (Ollafax, Rexapin, Olaxinn, Ozaprin Zyprexia). According to standard addition method, analytical recovery values were between 98-102% for each drug which showed applicability of the validated method.

In conclusion, developed and validated LC-MS method is accurate, sensitive, precise and linear. It can be used in quality control studies and routine analysis. Furthermore, this study can be improved for further analysis of olanzapine in biological fluids.

KEYWORDS: LC-MS, Olanzapine, Valsartan, atypical antipsychotics, validation, pharmaceutical formulations

REFERENCES: