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In situ/real time analysis in frame of COBAC, QSPR, QSAR and SBGN as a novel tool for the biosimilarity studies and physio-chemical prognostics in the biomedicine-assisted screening and experimental toxicology and allergology

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A current global trend in the development of biomedical and pharmaceutical chemistry is the use of computerized analytical technologies like COBAC, typically followed by the comparison with the action of the known analytes using QSAR/QSPR methods. The clinicians are interested not in the results of the primary measurements, but in representative results of the physiological and biochemical tests compared with the preceding drugs and their analogs. In this case, a direct conversion of numerical data into the QSAR/QSPR descriptor values with their subsequent transformation to the qualimetric results is necessary, which is described in this paper.

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Bioequivalence study of two rizatriptan formulations after single-dose administration to healthy male volunteers using liquid chromatography-tandem mass spectrometry (LC-MS/MS)

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Objective: The aim of this study was to assess the bioequivalence of two commercial 10 mg tablet formulations of rizatriptan, a selective 5-hydroxytryptamine1B/1D (5-HT1B/1D) receptor agonist indicated for the acute treatment of migraine attacks using a newly developed and validated LC-MS/MS assay.

Methods: A simple, sensitive and specific LC-ESI/MS method was developed and validated for the determination of rizatriptan in human plasma in positive mode using the transitions m/z 270.6-->201.6 for rizatriptan and m/z 384.07-->100.1 for the internal standard. Rizatriptan and the internal standard were isolated from plasma samples by liquid-liquid extraction. The chromatographic separation was accomplished on a Luna C18 (phenomenex) (50x4.6) mm, 5 µm with mobile phase consisting of acetonitrile: ammonium acetate (70:30 v/v) and 0.1% formic acid. A bioequivalence study was carried out in 24 healthy adult male volunteers using a single-dose, randomized, 2-way crossover design under fasting conditions. Both the test product and the reference product were administered after an overnight fast on two treatment days, separated by a 2-week washout period. After dosing, serial blood samples were collected for 12 hours. Statistical analysis of the pharmacokinetic parameters C_{max}, AUC_{0-12}, $AUC_{0-\infty}$ was conducted to determine bioequivalence.

Results: Intra-day and inter-day assay precision was acceptable. The lower limit of quantification was 0.1 ng/mL. Accuracy was observed over a linear range of 0.1-100 ng/mL. The differences between the two products did not reach statistical significance with 90% CIs of 91.3-112.6, 101.6-111.2 and 102.0-111.6 for C_{max}, AUC_{0-12} and $AUC_{0-\infty}$, respectively. The test/reference ratio of these parameters was within the acceptance range of the FDA criterion for bioequivalence. Both formulations were apparently well absorbed from the gastrointestinal tract (i.e., no specific gastrointestinal tract-related adverse events were reported).

Conclusions: The validated method offered increased sensitivity and wide linear concentration range. This method was successfully adopted for the evaluation of bioequivalence of two rizatriptan products after single dose administration to 24 volunteers.

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