Abstract

This thesis aims to statistically demonstrate whether mass-produced medicinal products can be used as an alternative source of reference materials for calibration in analytical chemistry. These preparations could be a potential alternative in cases where time is of the essence, for example in the clinical investigation of intoxication, if analytically certified reference material is not at hand. One of the most used methods in practice, high-performance liquid chromatography, was chosen as the analytical method. Like mass-produced medicinal products containing the active substances paracetamol and codeine were used, namely Panadol Novum 500 mg, Paramax RAPID 500 mg, Paramax RAPID 1 g, Paralen 500 mg, Codein Slovakofarma 28.72 mg and Talvosilen, which contains both mentioned active substances, namely 500 mg of paracetamol and 30 mg of codeine per tablet. Two different lots were tested for Paramax RAPID 500 mg. Potential sources of error were tested throughout the analytical process, namely weighing, solution preparation, and the measuring device. Each potential source of error was statically tested on two types of stock solutions using analysis of variance and Student's onesample t-test. It was statistically confirmed that the individually selected processes do not introduce errors in the analytical procedure. With the help of the obtained calibration dependence guidelines, it was further statistically proven that selected mass-produced medicinal products can be an alternative source of reference materials in analytical calibration.

Key words: calibration, high performance liquid chromatography with UV detection, mass-produced medicinal products, reference materials