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On the Importance of Pharmaceutical Analysis

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Editorial

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Pharmaceutical analysis by definition deals with analysis of drugs, pharmaceutical substances and raw materials. It is devoted to stability testing, comparing related substances (essential similarity testing of generics), determination of impurities and developing, implementing and applying active assays for the pharmaceutical industry. The complex tasks of pharmaceutical analysis may also include development of new pharmacopoeial methods, stress testing to validate stability-indicating methods, impurity analysis and identification, herbal or animal material analysis, cleaning validations, degradation tests and stability studies.

This definitely incomplete list indicates that a couple of semesters of analytical chemistry/pharmaceutical analysis included in the curricula of faculties of pharmacy around the world cannot possibly aim at providing the students with enough knowledge, skills and competencies to act as fully fledged pharmaceutical analysis professionals immediately after graduation. This is made even truer by development in the USA and Canada where faculties of pharmacy prepare only clinically oriented pharmacists with limited knowledge of pharmaceutical sciences. Professionals for pharmaceutical analysis are prepared in various study programs in pharmaceutical science. As pharmaceutical analysis continues to be shaped by extraordinary technological advances, it is very important that specialized studies in the area of pharmaceutical analysis are taking place. On the other hand, today's students in the pharmaceutical sciences are faced with the challenge of keeping pace with rapidly evolving methodology. Additionally, pharmaceutical quality control is performed today in broader framework of pharmaceutical quality assurance that also requires specific knowledge and skills.

Because of the challenges of the pharmaceutical analysis, inclusion of specialists from other field than pharmacy is becoming necessity. These are specialists in analytical chemistry, biochemistry, molecular biology and other fields. Consequently, pharmaceutical analysis became an area of real team work. This aspect is reflected also in the aims and scope of the Research & Reviews: Journal of Pharmaceutical Analysis by covering all the areas related to the pharmaceutical sciences. In this field, the analytical chemistry is an essential substance and integrating power for all branches of the pharmaceutical and biomedical research and development.

All new findings are linked with the use of proper analytical methods. In the past they were mainly various methods of chemical analysis while currently a wide scale of the instrumental analytical methods is preferred. In the frame of the instrumental analytical methods, the spectral, electrochemical and separation methods as well as their combinations are employed the most frequently. Here, hyphenated analytical methods such as high performance liquid chromatography coupled with mass spectrometry (and many others) have a unique potential in the analysis of pharmaceutical and biological samples as they combine

the sample preparation (e.g. concentration of the analyzed substances, elimination of the unwanted sample matrices, i.e. sample clean-up) with the identification and determination of the compounds of interest. In this way, the overall analytical procedure can be simplified and shortened. Moreover, the automation of the analysis is beneficial in preventing/reducing errors usually generated during external sample handling. Therefore, an integration of several valuable analytical steps into the single advanced hyphenation is one of the trends in modern analytical chemistry. Another one is a miniaturization of analytical systems such as lab-on-chip where consumption of chemicals and samples is minimized and analyses times can be considerably reduced. In these ways, very effective analytical methods can be developed for solving advanced tasks in pharmaceutical and biomedical research as well as routine laboratories. Nevertheless, just a well-defined research/application problem will properly determine a kind and complexity (advanced vs. conventional) of analytical method/procedure employed.

An evaluation of performance parameters is an integral part of each developed analytical method/procedure. Only the analytical methods/procedures approved by an appropriate validation protocol, i.e. methods producing reliable (precise and accurate) results, are suitable for their application in practice. Although a basic scheme of various validation procedures is similar (including parameters such as limit of detection, limit of quantitation, calibration line, linearity, precision, accuracy, recovery, robustness, selectivity), they are differing in particular parameters, e.g. related to the sample matrix, preparation, manipulation (e.g. freeze-thaw stability, specificity). Therefore the ICH (The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) guidelines are usually used in pharmaceutical analysis while FDA (Food and Drug Administration) guidelines are recommended for biomedical analysis. Only research with original ideas (novelty) and supported by properly optimized and validated analytical methods can be involved to the library of valuable scientific works building pharmaceutical and biomedical knowledge up.

As pharmaceutical analysis belongs among the most rapidly developing areas of science, any curriculum or educational program prepares specialists with knowledge that is 'outdated' very soon after graduation. Consequently, publications such as Pharmaceutical Analysis are essential in keeping awareness of the development in this field among relevant professionals modern and up-to-date. We would like to express our sincere gratitude to author, referees and the whole editorial team of Pharmaceutical Analysis for their contributions to the journal as this became an important source of scientific information.