



TOSOH

PHARMACEUTICAL ANALYSIS LABORATORY DEPARTMENT OF DRUG SCIENCES, UNIVERSITY OF PAVIA

Tosoh Bioscience: Could you give us a short summary of the research activities of your lab?

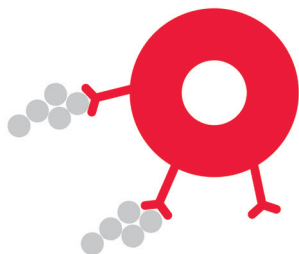
Prof. Massolini: We are essentially working on the development and application of novel methods in pharmaceutical and biomedical analysis by HPLC, coupled with diode array and mass spectrometric detection, like the development of stationary phases based on immobilized proteins/enzymes. We use the stationary phases as chiral selectors and biochemical probes for the determination of stereoselective ligand-protein binding interactions, ligand-ligand interactions and binding constants. We carried out innovative research on the exploitation of immobilized enzymes as bioreactors and have been involved in the development of frontal AFC-MS methods for drug discovery.

Which areas, besides the development of protein-based stationary phases, are you working on?

The experience in the field of immobilized macromolecules allowed us to direct the scientific interest to the development of bioreactors for the on-line digestion of proteins. We have developed new on-line HPLC-MS systems for the digestion/identification of proteins with particular regards to the characterization of post-translational modifications and for the analysis of biopharmaceuticals. Further research activities are devoted to the development and validation of HPLC methods for food and cosmetic products, quality control and pharmaceutical analysis for the assay of active compounds.

Your group is very open to co-operations with industrial partners. Where do you see the values in this type of projects?

We enjoy close collaborations with thought leaders in both academia and industry, that provide excellent input for the development of our research ideas. Discussion with experts from companies producing columns with innovative stationary phases, such as Tosoh, enabled us to improve the chromatographic methods that we design to tackle pharmaceutical and biomedical problems. HPLC columns provided by industrial partners are also used for the training of students in pharmaceutical analysis and help to overcome insufficient financial resources.



What do you think are the key challenges for the analytics of pharmaceuticals today?

The advent of protein-based biopharmaceuticals and antibody drug conjugates (ADCs) has resulted in increased reliance on the chromatographic and spectrometric techniques used to determine the key quantitative and qualitative attributes of such complex therapeutic entities. HILIC, in conjunction with tandem mass spectrometry (MS/MS), has steadily gained acceptance in the analysis of polar compounds from complex biological matrices. Another important issue is the characterization of genotoxic impurities. There is a demand of appropriate strategies used to select and develop analytical methods relevant for the particular impurities identified. In this context, HILIC as an HPLC mode orthogonal to reversed-phase, can be used by itself or in multidimensional approaches, for the separation of a variety of pharmaceuticals and their impurities in both R&D and Drug Discovery laboratories.

The University of Pavia is one of the oldest universities in Italy. Alessandro Volta (1745-1827) and Camillo Golgi (1843-1926, Nobel Prize 1906) are two of many of famous professors who taught in Pavia. The department of drug science is renowned for the high quality of research and application work and continuously publishes a broad range of scientific papers under the guidance of Professor Gabriella Massolini, the director of the department.

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