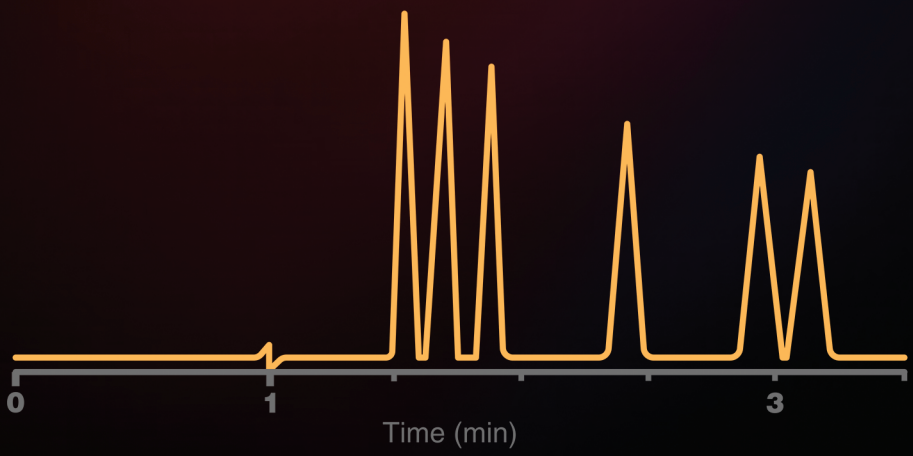
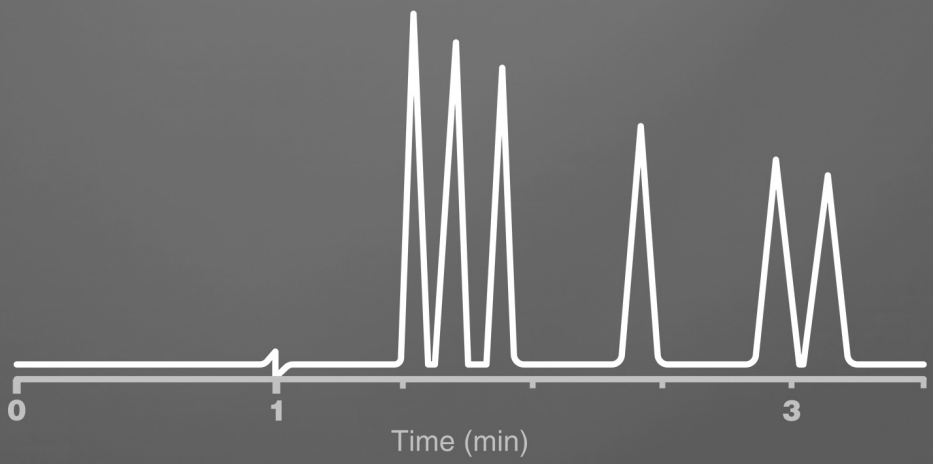
Jenny Stanford Series on Pharmaceutical Analytics — Volume 3

edited by
Gregory K. Webster | Laila Kott



Chromatographic Method Development



Chromatographic Method Development

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Preface

From Greg Webster

Years ago, when starting my industrial analytical chemist career, the company I started working for directly out of graduate school sent me to the HPLC Methods Development course by Lloyd Snyder and Joseph Kirkland. Having spent most of my graduate years on spectroscopy-related research, I was excited to "fill in the gaps" from the several chromatography courses I had taken. I knew my practical experience was lacking.

Snyder and Kirkland's love of chromatography was evident in their teaching. It was contagious and set the foundation for an analytical career that has spanned several decades and many chromatography applications. After moving back to Chicago, I was asked to teach a graduate chromatographic methods development class at Governors State University. The previous instructors focused the class on regulatory applications and requirements of chromatography. My view was that students need more method development theory to be successful in industry—regulations are not much help without suitable selectivity for the analytical method. The standard text for liquid chromatographic development is and remains Snyder and Kirkland's *Practical HPLC Method Development* and I used it for several classes.[1]

I joked after finishing my second book with Pan Stanford Publishing (now Jenny Stanford Publishing), *Poorly Soluble Drugs: Dissolution and Drug Release*, that never again would I take on such an undertaking.[2] I also realized an update in text was needed after driving home from a lecture at Governors State in which I was getting tired of telling students that they needed to focus on the principles of Snyder and Kirkland's text, mostly because the specific columns and instruments used in 1997 were no longer

[1]*Practical HPLC Method Development*, 2nd edition, L. R. Snyder, J. L. Kirkland, J. L. Glajich, ©1997, Wiley-Interscience, Print ISBN 978-0471007036.

[2]*Poorly Soluble Drugs: Dissolution and Drug Release*, G. K. Webster, J. D. Jackson, R. G. Bell (editors). ©2017, Pan Stanford Publishing, Print ISBN 978-981-4745-45-1.

in use in current industrial laboratories. For example, few of us will ever use a 250 × 4.6 mm column packed with 10 µm particles again. I told them my true life experiences of the battles I personally had with sister laboratories trying to get them to move from 5 to 3 µm particles and then ultimately having to do it all over again with UHPLC packings. After further reflection, I called my dear, very energetic and motivated friend and former co-worker Laila to see if she was interested in undertaking what at this time is truly to be my last chemistry book venture. I told Laila that no one rewrites a "bible." If we were going to do something, we had to be different. We decided on a text that covers not just liquid chromatographic methods development but all the methods that an industrial chromatographer may see. Our idea was born. Laila and I approached Jenny Stanford Publishing with our idea and outline of the proposed chapters. With their interest assured, we then contacted those we knew who were subject matter experts in their assigned chapter.

Of course, life and work get in the way. A text we hoped to complete in 2017 was finished in 2019. I thank Laila for the periods where she drove the bus. We both thank our authors for their expertise, patience, and efforts. My hope is that this text may help an aspiring chromatographer, as Snyder and Kirkland's text has helped me.

From Laila Kott

My path to this point has some similarities to Greg's and some differences. As an undergrad at the University of Toronto, I took my time to declare my major and after almost two years at the university, chemistry it was and still is. The difference is that there were always core functions of chemistry that I considered just part of the chemists' toolbox as I followed one research project after another. I made the materials I needed to study; I analyzed the materials I needed to study. I never considered myself a certain type of chemist, just a chemist.

Several degrees later and having taken a sabbatical from the scholarly life between my master's and doctoral degree to do chemistry in the former Soviet Union, I ended up in the pharmaceutical industry, where I found my journey through many different projects had afforded me a very strong background in a variety of analysis techniques. Since, as Greg mentioned above,

people often focus in one area or one technique, I found that looking at a problem using several different techniques often gave one a more complete picture of what you were looking at.

This was the exact time when Greg and I started collaborating and we have been tackling interesting problems as well as pharmaceutical industry standard problems ever since. We have always pushed the newest columns, the newest technology. This has its drawbacks as not all things new are readily accepted by the regulatory bodies during new drug filings. Nevertheless, we noted that there was a decided lack of method development information for the modern chromatographer out there, and this is our attempt to rectify the situation. We have had many challenges during the compilation of this book, but our drive never wavered as the need is out there. Happy separations!