

Interview with Dr. Avinash B. Chaudhary

GVK BioSciences, Hyderabad, India

Dr. Avinash B. Chaudhary leads the analytical department at GVK BioSciences located in Hyderabad, India. He is currently serving as a Principal Scientist at GVK and has more than 15 years of versatile experience leading analytical departments in various pharmaceutical and CRO companies in India. After earning a doctorate degree from the University of Mumbai, his career has been focused mostly around chromatography. He has sound knowledge in HPLC Method Development as well as Preparative purification process. He has served as SFC Application Specialist for a short period of time at Frankfurt, Germany for Waters and involved in establishing SFC purification facility to a greater extent at GVK. He is responsible for various activities including managing an analytical team, coordinating with clients for small as well as large scale purifications, method transfer process, providing assistance for resolving complicated structural elucidation issues and so on. He has established a lot of achiral as well as chiral purifications using SFC.

Phenomenex:

Which industry are you seeing the most growth, Pharma, BioPharma or Food and Bio-industries in regards to preparative purification applications?

Dr. Avinash:

I feel that the Pharma, BioPharma and Bio-industries would grow in coming years and the purification applications in these areas would increase. The food industry will also grow but the prep applications are not as great in this area. One industry that is growing fast is FMCG (Fast Moving Consumer Goods) and we do many types of these projects. These goods are basically the daily used consumer products such as soaps, soft drinks, biscuits, detergent, etc. This sector represents one of the leading economies in any country and the market size in India is ~\$14 billion USD, which is the fourth largest economy in the country.

Phenomenex:

Do you see the importance of maintaining GMP standards for the purification applications?

Dr. Chaudhary

Yes, we do see the importance of maintaining the GMP standards for purification applications. Many pharma companies are now using this technique to extract the very high potent drug from crude, which can directly be used in formulations, etc. and it is mandatory to have such facility.

Phenomenex:

What is the current market share and growth rate perceived for SFC technique in India?

Dr. Chaudhary

Current market share in the Indian subcontinent is very low and in the coming years we hope the technique would increase.

Phenomenex:

Even though SFC is an established technique for the chiral purification applications, what proportion of achiral applications were found successful in your experience?

Dr. Chaudhary

SFC chromatography is known for both Achiral and Chiral purifications. We have seen a 40:60 achiral to chiral ratio, but in coming years achiral separations may increase.

Phenomenex:

Do you have a general methodology or protocol for SFC method developments similar to the approach for reversed phase developments? What are the steps for R&D that needs to be done to elevate SFC to a kind of quasi-universal tool for purification?

Dr. Chaudhary

In achiral SFC we do have a generic method to screen the compounds but this is not the case for chiral SFC. The chiral selectivity is too widespread to come up with one generic methodology. Even though it is difficult to have a general protocol for the chiral SFC applications, I am confident that 80% to 90% of the applications can be easily achieved by using SFC. Analytical R&D scientists need to have confidence in this new technology but we need to keep in mind that every technology has its own limitations as well.

Phenomenex:

Do you have any strategy or ideas for transferring conventional HPLC applications over to the SFC technique?

Dr. Chaudhary

We do not have established strategies for transferring conventional methods to SFC, but we are confident we will have these in place in the near future.

Phenomenex:

What is the most serious limitation according to you in SFC technique?

Dr. Chaudhary

The limitations are wear and tear of replacement parts, calibration on preparative scale and there should be a lot of improvements in the injection part of the system for easier maintenance.

Phenomenex:

What is the practical maintenance cost of the SFC compared to conventional LC's?

Dr. Chaudhary

While running both systems 24 hours a day, seven days a week, it costs 5 lakhs (\$9,000 USD) more in maintenance and replacement parts for a SFC instrument than compared to a preparative HPLC instrument.

Interview with Dr. Avinash B. Chaudhary

Phenomenex:

What is your practical lifetime observation of preparative purification columns under SFC conditions?

Dr. Chaudhary

The lifetime of prep columns is more in SFC as compared with conventional HPLC purification systems and we have especially seen that Phenomenex chiral column lifetime is greater than the Daicel columns.

Phenomenex:

Do you observe a kind of anxiety or fear about this technique with the new investors or start-ups?

Dr. Chaudhary

Dr. Avinash: Yes, there are risks on the technical support and maintenance support with any new manufacturer or distributor. The cost and availability of replacement parts are also a concern as this may lead to prolonged instrument downtime.

Phenomenex:

Who are the key players in SFC and who has the major share in India and why?

Dr. Chaudhary

Obviously Waters SFC is the major one but it does have many drawbacks when compared with PIC Solution SFC.

Phenomenex:

What do you expect from a stationary phase manufacturer in terms of availability, choice of phase, delivery time, and financial stability?

Dr. Chaudhary

We expect the stationary phase should be quite stable and resolution should be good and durable. We also need phases that are compatible with all the common solvents and buffers. Products should be available within a week or 2 weeks time.