

## HPLC Market in India

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It was in 1983 from IIT Chennai, Spinco got the first order for Shimadzu HPLC in India. It took 13 years for Spinco to reach an installation base of 1000 HPLC systems and four more years to reach the landmark of 2000 systems by the year 2000. The buoyancy in the market fuelled the HPLC business and in the next seven years 4000 plus systems were added. In quick succession in two years now, Spinco celebrated 1000 sets of LC 2010 High Throughput Integrated HPLC and 1000 sets of modular Prominence HPLC. From the first installation in 1983, Shimadzu has come a long way to cross 6500+ installations today. This is not just the story of Shimadzu HPLC, in fact, this is the history of the evolution of HPLC market in India over the last 25 years.

HPLC which was once a privileged instrument has transformed today to an indispensable tool for routine applications in every laboratory and in every industry. The change was catalyzed by the liberalization of government policy, growth in the pharmaceutical industry and propelled now by the major advances in instrumentation and column technology.

### What is HPLC

Chromatography is a process whereby a mixture of materials is separated by forcing it to pass through a medium, which selectively interacts with the different components. As the mixture is carried along through the medium, this selective interaction causes the different components to travel at different rates and thus get separated. Chromatographic techniques are generally identified by the phase of the carrier material used – Liquid Chromatography, Gas Chromatography, Supercritical Fluid Chromatography, etc.

The origin of Liquid Chromatography was the studies of Mikhail S Tswett in early 1900 on the separation of leaf pigments using solvents. Although liquid chromatography was the first chromatographic technique developed, it did not become highly useful until the development of HPLC in the seventies. The name 'HPLC' originally referred to the fact that high pressure was needed to generate the flow of solvent in packed columns. However, with continued advances in instrumentation and development of packing materials, the name was changed to High Performance Liquid

### Market Dynamics in India

- ⇒ The present Indian market for HPLC and its accessories is \$ 125 Million with an estimated growth rate of 20 -25% per annum.
- ⇒ By fiscal year 2010, HPLC business is expected to grow to \$ 250 Million.
- ⇒ Among the estimated 2000 plus HPLC units supplied every year now, the pharmaceutical market accounts for around 70%.
- ⇒ Fast LC is expected to have a growth rate of 20%. Following Waters other vendors have also brought out Fast LC now.
- ⇒ The HPLC columns sold in India will be around 60,000 numbers in 2007, valuing around \$15 million. This will grow by 25%.

Chromatography that improved separation, identification, purification and quantification far above the previously known techniques. Computers and Automation made HPLC more popular.

### HPLC in the Analytical Instrument Industry

The worldwide market for Analytical and Life Science instrumentation for 2006 was estimated to be around \$ 33 Billion. The HPLC market including supply of accessories, columns and consumables was the largest segment totaling to \$ 3.2 Billion. The compounded annual growth for HPLC is forecasted at 6% per year for the next few years bringing estimated revenues to nearly \$ 4 Billion by the year 2010.

Despite the absence of published data, the Indian market for Analytical and Life Science instrumentation may be estimated to be close to \$ 1000 million for the fiscal year 2006 – 07 in which the share of HPLC and its accessories was \$ 125 Million. The market is witnessing strong growth opportunities of 20 - 25% for HPLC in the coming few years and by fiscal year 2010 the total HPLC market of India is expected to grow to \$ 250 Million.

### Indian HPLC Market – Past Scenario

In late seventies, there were just three vendors for HPLC – Waters represented by Material Research Instruments, DuPont promoted by IR Tech and LDC Milton Roy, distributed by Marsap. Early eighties brought a few more – Spectra Physics (Toshniwal Instruments), LKB ( SICO ) and

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Micromeritics (Scientific Aids). In 1983, Shimadzu appointed Spinco as their distributor for HPLC.

In the pre-liberalization era the import restrictions were high. A 'Not Manufactured in India' certificate and a 'Duty Exemption Certificate' were mandatory for import – the process for ordering a HPLC was more than a one year project. With the government liberalizing import in 1991, more industries started ordering HPLCs. The liberalization was followed with gradual reduction in customs duty year after year.

It is interesting to look back nearly 25 years later today that other than Shimadzu and Waters, none of the other brands of eighties exist in the market now. In the case of Waters, the distributors were changed to Salesworth in eighties and Waters became a direct subsidiary in mid nineties.

### Indian HPLC Market – Present Scenario

The Indian pharmaceutical industry with annual sales of over \$9 billion, ranks 13th in terms of value and 4th in terms of volume globally. It is expanding at a compounded annual growth rate of over 10%. This resulted in tremendous increase in the number of quality control, method development, research and drug discovery laboratories. This is the driving force for the HPLC market. The demand is further fuelled by the rise in contract research and bioequivalence business opportunities. The surge in demand for LC MS in the Indian market is also a factor for the growth in the HPLC market. The technological advancements with advent of systems for faster analysis have also opened up newer opportunities of growth. Among the estimated 2000 plus HPLC units supplied every year now, the pharma market accounts for around 70%. Proteomics and other life science applications have propelled the growth in academia and biotech industries, accounting for about 10%. National Laboratories and other government institutes are also a major segment for HPLC with equal share. There are host of other non-pharma industries like chemical, pesticide, food and beverage, etc who also use HPLC extensively. The demand from independent testing labs is increasing due to continued outsourcing from pharmaceutical industries. These segments will account for the remaining 10% share of the market

### HPLC Product Categories

HPLC is one of the most dynamic markets in the analytical instrument industry. The market can be segmented into four broad categories - Analytical HPLC accounting for 80% of the market. Ion Chromatography, Preparative HPLC and LC MS are the other three segments.

Ion Chromatography is an off-shoot of general liquid chromatography in which the detector used is conductivity. Ion Chromatography was originally developed to analyze inorganic anions and cations, catering initially to the environmental laboratories. However, today it finds wide applications in pharmaceutical and biotechnology laboratories also. The two leading players in this segment are Dionex and Metrohm. There is a separate exclusive review on Ion Chromatography.

Preparative HPLC systems are ideally used for impurity profiling, drug discovery applications, high throughput screening and purification. Besides the three HPLC majors - Agilent, Shimadzu and Waters, preparative HPLC is also offered by Varian, Gilson and Knauer LC MS is the fastest growing technique, thanks to the explosive growth in clinical trials, pharmacokinetics and drug metabolism studies. LC MS is reviewed separately with other MS techniques in another article.

There are also dedicated systems like Gel Permeation Chromatograph/ Size Exclusion Chromatograph for molecular weight distribution studies, Amino Acid Analysis system, 2D HPLC for Proteomics research, Nano HPLC for LC MS applications etc. These systems have limited requirements but have a fast growth dynamics today.

### Fast LC – An upcoming trend

Fast LC is indeed the growth engine today contributing to the enhanced growth of analytical HPLC. This technique is gaining wide popularity with a growth rate of 20% as per market study. Fast LC applications can be accomplished with either elevated temperatures or increased pressure. It is difficult to say which approach has the technological edge.

In 2004, Waters introduced Acquity UPLC – Ultra Performance Liquid Chromatograph using columns packed with particle sizes of 1.7 micron and advances in instrumentation designed to deliver 15000 psi. Quickly following Waters other vendors have also brought out Fast LCs with similar objective but having compatibility with standard HPLC equipment. Agilent offers RRLC - Rapid Resolution Liquid Chromatograph mentioning that the method developed on a conventional HPLC can be transferred seamlessly to a RRLC. Shimadzu has launched UFLC - Ultra Fast Liquid Chromatograph offering high throughput but without high pressure. Dionex achieves Fast LC with Acclaim Fast column with UltiMate 3000 Intelligent LC. Thermo has launched Accela High Speed LC that has been designed to optimize performance of sub-two micron particle columns and upto 15000 psi.

The issues to be settled for Fast LC are: sample integrity, sample throughput, sensitivity, method development (optimization), initial investment and maintenance cost etc.

### Market Players - HPLC Systems

The competitive landscape has changed significantly over the years from the eighties when there were very few players. Today, from Agilent Technologies to Zirchrom Separations, there are close to one hundred companies offering HPLC related instrumentation and services. However, the leading three brands in India are Agilent, Shimadzu and Waters. The huge demand for HPLCs and various selection criteria enable robust growth for all players.

There has been a paradigm shift in the distribution channels over the last decade. The increased market potential has seen many global players setting up either a direct subsidiary or a joint venture with their erstwhile distributors. Those who have



established subsidiaries are : Agilent, Biorad, Beckman – Coulter, GE Healthcare, Perkin Elmer, Sigma Aldrich, Thermo Fisher, Waters and Varian. Dionex and Metrohm have joint ventures. Chemito has OEM arrangement with Knauer. Shimadzu, on the other hand reinforced its successful distribution strategy by establishing Customer Support Centers in India . The other manufacturers who have distributors are : Jasco, Hitachi, Gilson etc.

### Market Players - HPLC Detectors

Detectors form a major part of the HPLC aftermarket. The detectors equipped with flow thru cell were a major breakthrough in the development of modern liquid chromatography. Since sample compounds have differing characteristics several different types of detectors are currently available for HPLC. The detectors are chosen based on the type of analytical information required. The current LC detectors have wide dynamic range normally allowing both analytical and preparative scale runs on the same instrument. They have high sensitivities to detect nanograms of material.

The popular detectors are UV-VIS, Photo Diode Array, Refractive Index, Fluorescence, Evaporative Light Scattering, Electro Chemical, Radioactive and MALLS. Diode Array Detectors can measure the eluate at several different wavelengths simultaneously in addition to the ratio between two extinctions. Using multiple detectors in series such as a UV or ELSD detector in combination with a Mass Spectrometer is a powerful approach to gain maximum information. Single Quad Mass Spectrometer as a detector for HPLC is gaining popularity. Of late LC-NMR is also being used to get excellent spectra allowing structural elucidation.

While all the major HPLC manufacturers offer generic detectors like UV-VIS, Diode Array, Refractive Index, Fluorescence, etc. there are specialized vendors for application specific detectors such as IN-US for Radioactive Detector; Alltech, Polymer Labs (now Varian) and Sedex for Evaporative Light Scattering; Antec Leyden, BAS & ESA for Electro Chemical Detector, Wyatt for MALLS. Application specific systems built on such special detectors are also offered such as, High Temperature GPC by Polymer Labs and Viscotek, Alexys LC-EC system by Antec, Dynamic Light Scattering Systems by Wyatt etc.

### Market Players - HPLC Columns

Columns are the largest segment of HPLC aftermarket, which is rapidly growing, thanks to the continued development of new column technology and applications. Newer stationary phase technology like monoliths, hybrid particles, sub 2-micron particles and extended temperature and pH columns are adding new dimensions. Validation and productivity demands of modern laboratories is the major growth driver.

The estimated number of HPLC columns sold in India will be around 60,000 for the year 2007 valuing around \$15 million with a growth rate of 25% per annum. The major suppliers for columns are : Waters, Thermo, Merck, Agilent, GL Sciences, Phenomenex, Daicel, YMC, Sigma Aldrich, Machery Nagel,

Whatman etc. One of the companies – Flexit Laboratories, Pune ( now acquired by Grace Discovery Sciences ) is locally manufacturing HPLC columns. In view of the increased demand for chiral columns, Daicel Chemical Industries has recently set up a Technical Support Laboratory at Hyderabad.

### Strategic Corporate Developments

As it happens in other trades - mergers, acquisitions and strategic co-operation is the order of the day in HPLC business also. For instance, just in the month of October, Thermo Fisher acquired La-Pha-Pack, a company specializing in HPLC vials and also there was a change in ownership at Antec Leyden, a Netherlands based Electrochemical systems manufacturer. Another significant development is a collaborative effort between the two major HPLC vendors - Waters and Shimadzu wherein the Empower software will seamlessly control Prominence HPLC.

### Looking 2007 and beyond

To sum up, the present favourable market dynamics in India coupled with the technological advancements in instrumentation will undoubtedly make HPLC the fast growing technique amongst other analytical instruments. ■