

ANNUAL REPORT 2004-05

innovationinspired





### innovationinspired

In a glittering ceremony on the evening of December 14<sup>th</sup>, 2004, His Excellency Dr APJ Abdul Kalam, The President of India, inaugurated our research centre SPARC, in Baroda. For the team at Sun Pharma, this was an event of solemn significance that places our foray into drug discovery innovation on a new platform altogether. This event gave impetus to a new way of looking at ideas, of creating work that can earn intellectual property. It bestowed a fresh confidence to reevaluate what is seemingly apparent. Against a different perspective sometimes what is obvious can present a new idea, a new path to a solution, perhaps someday an opportunity that can be reaped across world markets.

This approach to "seeing" is what the cover signifies, in the artist's representation of a crystal.

In crystalline forms, atoms or molecules are lined up in an orderly arrangement and connected by bonds, and these atoms or molecules have a repeating pattern known as lattice. Atoms or molecules in these crystal structures are held together by electrical forces or non bonding interactions such as hydrogen bonds in incredibly large numbers to form visible shapes-cubic, tetragonal, orthorhombic, monoclinic, hexagonal...depending on the prevailing conditions, or environment, a single substance may occur in more than one crystalline form in nature. Each of these would exhibit a different set of chemical and physical properties.

Each of these could be a starting point to a new idea or a new process. The difference is in the prevailing conditions, as much as in the perspective, and an openness to look at differing probabilities and outcomes.

"I visited just now SPARC, and I was very happy that such an important institution has come up in this part of the city, and I also realized the two important contributions, one in the medicinal area, that is biodegradable injectable drugs, and that's a very good effort what has happened in SPARC. Second one, the confidence that we can do it, that means from molecule to drug... the confidence, that's the most important thing."

- excerpt from H. E. Dr. API Abdul Kalam's speech



His Excellency Dr. APJ Abdul Kalam, The President of India, inaugurated our research centre SPARC, in Baroda, on 14th December, 2004



Turnover for the year ending March 31, 2005 was up 23%.

Domestic formulations, which is the sales of speciality prescription brand in India is the largest chunk of our business, grew 18%.

International formulations, a priority area for the company, grew 27%.

Export of speciality bulk actives grew 40%, driven by increasing number of international approvals for drug master files

Technical capability encompasses bulk actives including anticancers that are made under highly controlled conditions and a range of formulations

In the domestic market, Arian, Symbiosis and Radiant were the top 3 divisions in terms of growth with fairly high stretch, difficult targets.

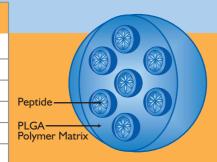
Formulations for the domestic market are now largely sourced out of 2 large sites that offer tax benefits, in Jammu and in Dadra.

Exports of branded prescription drugs, to markets other than the US, have been growing at 40% plus for the third year in a row, as we implement the same focus and intent that has served us so well in the domestic market. We are excited about the potential that the international markets offer, specially as we rollout new products, including products with a technical complexity like Lipodox and Lupride Depot, which are under registration in some of the neighboring markets. We continue to be extremely careful about the resources that we commit to each market, and even in the investment phase, these have not been disproportionate to our earnings from that market. This conservatism, respect for profits and a willingness to modify the basic model in order to do whatever is required in a particular market is a key factor of our operations.

Speciality bulk actives was 17% of turnover, a growth of 17% across domestic and international. Increasing US sales at our subsidiary, Caraco, building on the advantage of backward integration, have helped it compete more aggressively in the competitive US generic market.

(Rs. Mill)

Sales Breakup by type <sup>#</sup>	Mar 05	Mar 04	
<ul><li>Domestic Formulations</li></ul>	6800	5778	
<ul><li>Domestic Bulk</li></ul>	908	960	
<ul><li>Others</li></ul>	8	-	
<ul><li>Export Formulations</li></ul>	3690	2900	
Export Bulk	1345	961	
<ul><li>Export Others</li></ul>	2	2	



Inside Lupride Depot: Leuprolide Microspheres
Over half the products launched every year have a delivery
system advantage or technical complexity

Divisionwise representative

strength

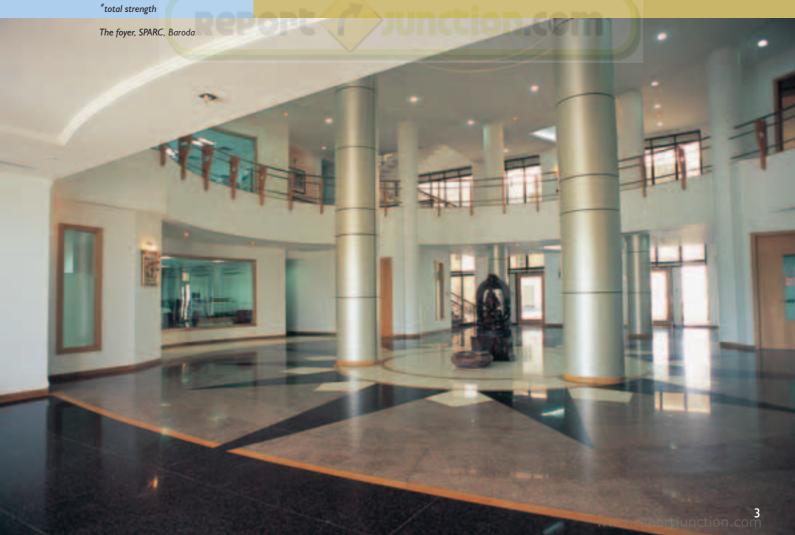
(March 05)

Sun	263
Spectra	230
Solares	249
Arian	168
Aztec	167
Synergy	113
Milmet	70
Avesta	69
Symbiosis	91
Sirius	85
Inca	86
Onco	<b>36</b> <sup>#</sup>
Radiant	80
Ortus	57
Athena	22#

A field force, divided by speciality therapy area, speaks the customer's language; this speciality focus earns customer trust and prescription share

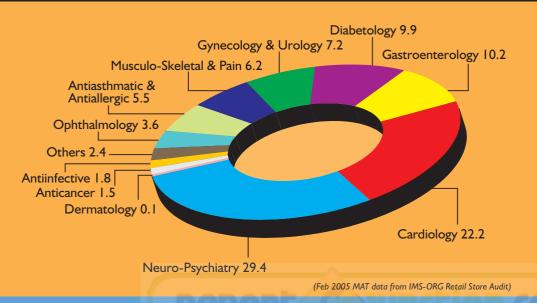
## C-MARC RANKS

	NOV 02 to MAR 03	MAR 04 to JUN 04	MAR 04 to JUN 05
<ul><li>Psychiatrists</li></ul>	1	1	1
- Neurologists	1	1	1
<ul> <li>Cardiologists</li> </ul>	3	1	- 1
Ophthalmologists	4	3	1
Gastroenterologists	3	2	2
Diabetologists	3	4	2
Orthopedics	6	4	3
Oncologists	6	8	3
Chest Physicians	4	4	5
Consultant Physicians	5	5	5
<ul> <li>Gynaecologists</li> </ul>	11	7	8
- ENT Specialists	5	9	9





Bulk active plants can handle high pressure, volatile reactions



domestic prescription sales, and for important products we make the bulk active



# THERAPY WISE BREAK-UP (%)

Our speciality bulk active list comprises of high-end speciality drugs that have fairly stable margins and a few manufacturers the worldover. Of specific interest here is the capability that has been created to handle products like anticancers, steroids, hormones and peptides- all of these need controlled manufacturing conditions. The cephalosporins market, specially that of third generation cephalosporins has in the recent years, witnessed a change in the pricing structure with several manufacturers exiting cephalosporins to make higher margin products. This extensive opportunity with higher end cephalosporins is the reason for the acquisition of Phlox Pharma. In the 2-year timeframe that the merger proposal has taken through legal/ regulatory framework, extensive work has been done to create a formulations facility for both sterile and non-sterile formulations that would meet stringent regulatory standards such as the USFDA. This formulations plant would be operational in the first half of 2005-06. Capability with sterile formulations and bulk actives will help us make inroads into markets where we have at best been a marginal player with low margin cephalexin sourced out of the erstwhile Gujarat Lyka plant, a business that was subsequently discontinued due to changing business dynamics.

As many as 8 bulk actives and 18 processes for DMFs\* were developed and scaled up. In all, 7 DMFs and 9 EDMFs have been received, 29 more fillings for US and Europe have been made and are awaiting approval.

(\*DMF: Drug Master File; EDMF: European Drug Master File)

Anticancer process development; SPARC



# Research & Development





Above: SPARC Baroda and SPARC Mumbai

# Across 137 labs over four floors, this research center now is staffed with close to 355 scientists.

During the course of this year and the last, additional 250,000 sq ft of research floor area across 2 high capability sites was added in Baroda and in Mumbai. This will help your company take ahead exciting projects in new chemical entity (NCE) and novel drug delivery systems (NDDS), bulk actives and formulations with renewed focus and enthusiasm.

At Baroda, the new chemical entity facilities enable us to take ahead a project from idea through animal testing and preliminary testing in humans under one roof.

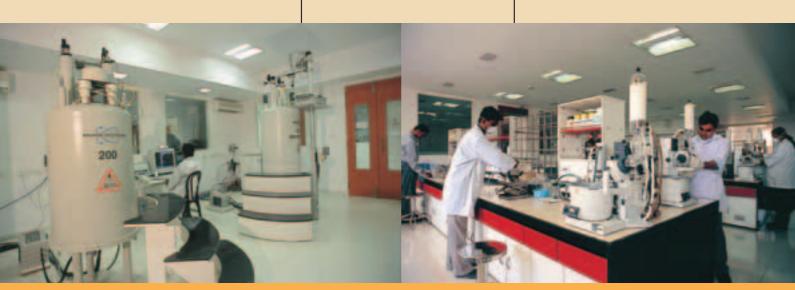
Across 137 labs over four floors, this

research center now is staffed with close to 355 scientists.

Our Mumbai research facility offers a state of the art pharmaceutics lab over 50,000 sq ft with 65 scientists offering technical support for our US projects, primarily for Caraco.

While our longer term projects are in the areas of NCE and NDDS, focus has also been maintained on medium to short term programs for projects that address India and the neighboring markets. This year, we brought over 40 products to market, over a half of which were delivery system based or had a complexity in manufacture, and

have 22 products for the US/ European markets filed and awaiting approval. Cumulative to March 2005, 35 patents had been received and another 399 filed and awaiting approval. Processes for 26 bulk actives had been scaled up (including processes for US/Europe filings) and this list has complex products like capecitabine, flucticasone, imatinib polymorphic forms and tiagabine. Our priority is to balance both aspects- the dependable revenue stream delivering projects and the new to the world and exciting projects that may be uncertain but will deliver qualitatively and quantitatively superior revenue streams.



NMR labs at SPARC, Baroda and Process Chemistry labs: Deciphering the 3D arrangement of molecules crafted through new processes

#### INDIAN MARKET

This year, we introduced over 40 products (not counting line extensions) across marketing divisions. Some of the products were based on delivery systems that are not easy to replicate. The driving idea behind these technologies is to bring to market a product that offers quality of life advantages to the patient. (See the notes on Lupride Depot and Lipodox- drug delivery systems that we are excited about)

The table on the right lists a few of the delivery systems or complex technologies. These products, on account of the difficulties in development and design are not likely to be brought to market by competing companies, unlike other undifferentiated products that are easier to make. Our familiarity with these technologies places us in the right position to take this knowledge a step ahead with exciting, new to the world work.

### **DRUG DELIVERY SYSTEMS** XL/CR including gastric retention systems, multiparticulate systems

Month/week long biodegradable depots

Liposomal drug delivery

Ophthalmic gels

CR/SR

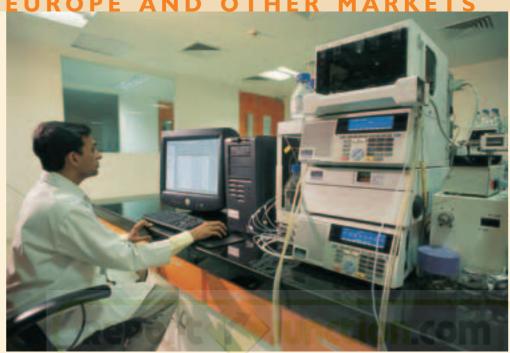
Mouth dissolving

DPIs/ metered dose, Nasal sprays



One of the dosage form product development suites at SPARC, a scaledown of an actual production area; a view of the analytical labs, SPARC Baroda

US GENERICS, EUROPE AND OTHER MARKETS



In the pharmacokinetics labs, SPARC; tracing minute quantities of drug in the blood stream to establish bioavailability

A dependable pipeline of filings is imperative for continuing success in the US generic market. Since the US market is prone to increasing pricing pressure, a continuously replenished pipeline of generics ensures that margins remain healthy going forward. With this year's filings we have in all 22 ANDAs awaiting approval between Sun Pharma and Caraco, some of which address interesting high growth opportunities. As an Indian company we are ideally placed to make good use of our quick product development ability, low cost manufacturing base and capability to make a product starting from the bulk active, in order to compete in this lucrative market.

The European market, while an exciting opportunity, is best served using a partnership approach. We seek to license out our products to an existing player, using our technical capability to develop and manufacture the product in India.

In the global markets, our intent is to launch products of technical complexity so that the products will deliver value to the patient and a brand can be established. Cummulative 350 registrations await approval across these markets, and another 739 registrations have been received. A foothold has been created in Brazil with a subsidiary established, and this is likely to emerge as one of the key markets going ahead.