

Report



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## BACK-END SHOPFLOOR TO THE WORLD



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Granules India Limited • Annual Report 2004-5

FORWARD-LOOKING STATEMENT

In this Annual Report we have disclosed forward-looking information to enable investors to comprehend our prospects and take informed investment decisions. This report and other statements - written and oral - that we periodically make contain forward-looking statements that set out anticipated results based on the management's plans and assumptions. We have tried wherever possible to identify such statements by using words such as 'anticipate', 'estimate', 'expects', 'projects', 'intends', 'plans', 'believes', and words of similar substance in connection with any discussion of future performance.

We cannot guarantee that these forward-looking statements will be realised, although we believe we have been prudent in assumptions. The achievement of results is subject to risks, uncertainties and even inaccurate assumptions. Should known or unknown risks or uncertainties materialise, or should underlying assumptions prove inaccurate, actual results could vary materially from those anticipated, estimated or projected. Readers should bear this in mind.

We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.



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GRANULES INDIA LIMITED  
SERVICES THE GROWING  
OUTSOURCING NEEDS OF  
GLOBAL CUSTOMERS THROUGH  
PRESENCE ACROSS THE  
PHARMACEUTICAL VALUE  
CHAIN – APIs, PFIs AND  
FINISHED DOSAGES

## OUR BUSINESS




To provide product outsourcing services to the global pharmaceutical industry.

## OUR VALUE CHAIN

From the manufacture of APIs and PFIs to the filing of ANDAs and Dossiers to the manufacture of solid dosages, resulting in a one-stop integrated solution.

## OUR PRESENCE AND FACILITIES

Headquartered in Hyderabad in India with an international presence through a wholly owned US marketing subsidiary. Our manufacturing facilities are located around the city of Hyderabad and are benchmarked to international quality standards.

LOCATIONS		FACILITY	CAPACITY	APPROVALS
Jeedimetla		PFIs	1200 TPA	Australian TGA / German HA /US FDA
		APIs	1041.60 TPA	US FDA WHO cGMP compliant
Bonthapally		APIs	3600 TPA	Certificate of suitability – EDQM
		APIs	8000 TPA	Under implementation
Gagillapur		Granulation	7200 TPA	US FDA / German HA/ Australian TGA
		Finished dosages	6 billion tablets per annum	Under implementation

## OUR ASSURANCE

'Quick to market at the lowest cost' solutions without compromising on quality.

## OUR CORPORATE OBJECTIVE

To emerge as the preferred outsourcing partner of major global pharmaceutical manufacturing companies and a one-stop shop offering a suite of products from finished dosages to PFIs to APIs and other customised products.

## OUR REACH

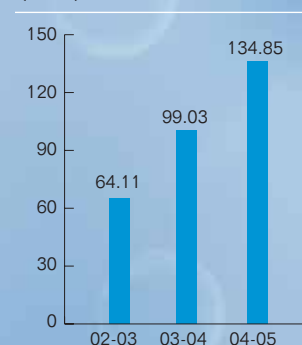
Exports to global leaders in USA, Germany, Mexico and Australia among 35 countries.

## OUR INVESTOR PRESENCE

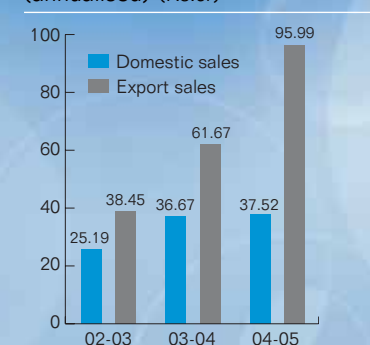
Listed on the Mumbai, National and Luxembourg Stock Exchanges, enjoying a market capitalisation of Rs. 132.42 cr as on 30th June 2005 (Rs. 64 cr on 30th June 2004).

## OUR PERFORMANCE

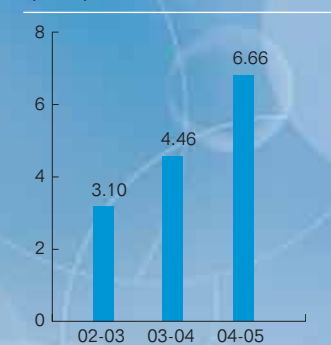
**Total income (annualised)**  
(Rs.cr)



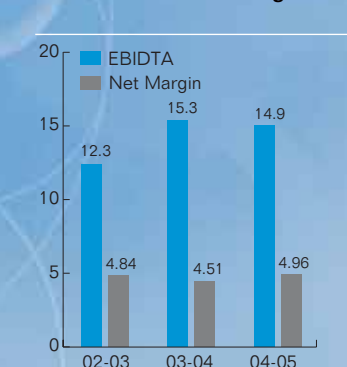
**Domestic and export revenues**  
(annualised) (Rs.cr)



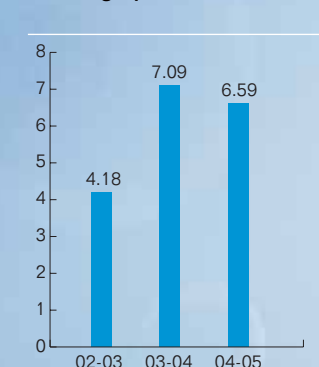
**Profit after tax (annualised)**  
(Rs.cr)



**EBIDTA and Net margin (%)**



**Earnings per share (Rs.)**





Chairman's strategy audit

"WE ARE AT THE RIGHT POSITION AT THE RIGHT TIME TO ENHANCE VALUE IN AN ATTRACTIVELY SUSTAINABLE WAY ACROSS THE FORESEEABLE FUTURE"



*Dear Shareholders,*

The basis of outsourcing is simple: a number of companies are dedicated to a focused competence in select areas of their broad businesses. This implies that there are areas where others are better.

As competitive businesses, we strive to reinforce what we are good at and seek to become better at what we are not. In an insular world, companies would try and do both by themselves; today's environment is less forgiving. This forms the basis of pan-global outsourcing: what we are good at we try and do, what we are not good at we get others to do it for us.

A universal drive towards generic drug formulations has increased competition within the industry and reduced the sticker price of most pharma products; besides, there is an increasing pressure by governments to make health care and medicines more affordable. The result: an increasing number of companies are getting specific product segments outsourced to external agencies with corresponding cost, time and convenience advantages.

The outsourcing movement could not have come at a better time for the global pharmaceutical business: there is a greater respect for patents across more erstwhile non-conformers today than ever before, making the outsourcing of protected products safer; there is a win-win proposition through which vendors can provide manufacturing outsourcing while customers can liberate their resources to focus on cutting-edge research and development; there is a significant arbitrage between the wage costs of the developed and developing economies; countries like India possess significant synthetic chemistry competencies coupled with sophisticated quality systems that make relevant companies a faithful extension of some of their developed market customers.

Granules India Limited is one of them.

The Company, I am pleased to say, is emerging as a preferred outsourcing partner of a number of global

pharmaceutical majors for various credible reasons:

- It pioneered the concept of commercialising the manufacture of directly compressible granules (PFIs).
- It is one of only four global companies in its space to have received regulatory approval for its PFI plant from the three major regulatory agencies – USFDA, Australian TGA and German Health Authority.
- It possesses the capability to manufacture PFIs in a single batch size of 6000 kgs, helping reduce costs for customers.
- It is integrating forward into finished dosages and dossier filings, emerging as an integrated solution provider.
- Its backward integration is being strengthened by the creation of additional capacities for some of the strategic APIs.

The Company is now extending its footprint to other hitherto untapped markets such as Russia and other CIS countries, South East Asia and the Middle East.

As a company dedicated to making its customers more competitive, we are extending from product to service delivery: we will provide dossier filings and value-added technical support to customers to make ourselves an integral part of their growth and development.

In view of this exciting industry environment, I am pleased to tell shareholders that the Company is in the right position at the right time and will enhance value in an attractively sustainable way across the foreseeable future.

Sincerely,

**Dr. C Nageswara Rao**  
Chairman

An overview by the Managing Director

# "WE STRENGTHENED OUR BUSINESS DURING 2004-5 THROUGH VARIOUS BACKWARD AND FORWARD INTEGRATION INITIATIVES"

## What aspect of the Company's performance was a source of satisfaction during the year under review?

During 2004-5, our business direction continued to be the same, only that we strengthened it through various initiatives. For instance, in a business as competitive as ours we need scale and value-addition. To address this we possess a PFI facility to manufacture multiple PFIs in single batch size of 6000 kgs. During the year under review, we embarked on the second initiative: backward integration into the manufacture of APIs through our first facility being set up for manufacture of Paracetamol with an installed capacity of 8000 TPA. We are also integrating forward through a proposed USFDA-benchmarked finished dosage plant with an installed capacity of six billion units per annum.

## In what way did the Company strengthen its customer acceptability?

The Company recognised the need to market to brand-enhancing customers in regulated markets as a means of protecting its revenues and insulating itself from competition. To enter these markets, it is imperative to possess confidence-

enhancing certifications. So the Company strengthened its plants, processes and practices in this direction: as a result, the PFI plant at Gagillapur received an approval from TGA (Australia), making the Company one of only four in the world in its business to have received approvals from all three major regulatory agencies like USFDA, German Health Authority and TGA. As an extension of this commitment, the Company's facilities were successfully audited by global customers leading to business and repeat income from existing customers.

## You indicated that PFIs is a competitive business. How did the Company counter this reality?

The Company embarked on distinctive initiatives in this regard: it widened its product portfolio leading to a one-stop customer convenience leading to growing customer relationships. On the other hand, an optimal product mix translated into stronger margins. So this approach had a dual benefit: increased off take and improved margins.

Concurrently, the Company strengthened its marketing with a direct presence in USA, which helped strengthen market share in North America, the largest pharmaceuticals market in the world. We now also have a direct representative in South America for marketing and client servicing, who is just 24 hours away from any customer within that region.

## You indicated a forward integration into formulations. How will this enhance value?

Success in our business is driven by one word: relationships. Companies that can extend one-off transactions into long-term relationships are likely to keep their customers and enhance business sustainability across various industry cycles. Over the years, we did so by having a number of brand-enhancing global customers enter into long-term outsourcing relationships with us.

Gradually, a number of customers have requested us for finished dosages in addition to our PFI service. This will serve a win-win proposition: help our customers outsource the entire manufacturing process from API to PFI and formulations, migrating us to a higher value chain.

To enhance the sense of convenience, the Company is building competencies that will enable it to file various regulatory dossiers like ANDA filings, thereby supporting the business of its customers in helping them bring their prescription products faster to the market.

## What competencies will enable this to happen?

To enable us to integrate forward we are setting up a contemporary R&D facility. This facility will offer a number of advantages: comprise a pilot plant enabling us to scale from the lab size to pilot batches and enable us to carry out

various bio equivalence studies. Besides, we have recruited senior experts from relevant fields to drive our formulation and R&D operations. We have also intensified training efforts across functions and especially on regulatory competencies to ensure that our team is constantly trained in new practices and regularly updated on the industry developments.

## Even as you integrate forwards how are you strengthening your backward integration?

Our 8000 TPA capacity API (paracetamol) plant at Bonthapally is expected to go on stream by January 2006. This plant will enable us to balance the 6 tonne batch size of our PFI plant at Gagillapur and reduce sampling costs. We are also extending our backward integration to focus on the manufacture of niche APIs. This will help us substitute the manufacture of costly imported APIs with our own product.

## People are obviously going to be important for this. How does the Company expect to strengthen its intellectual capital?

At Granules, we recognise that it is our people who will help us successfully respond to the emerging challenge. In view of this, our HR team is working to enhance a culture of motivation, accountability and appraisals. We are also strengthening the organisation through the recruitment of experts: from two to five in the US.

## What is the Company's outlook for the current financial year?

With increasing competition, declining drug prices and governmental pressure on price reduction, the need for cost control and consequent outsourcing is more now than ever before. This comes at an opportune time: with India becoming product patent respecting, the global industry is looking favourably at India for its outsourcing needs.

Granules is attractively poised to capitalise on this opportunity through its product integration, more than a decade's experience, niche product range, GMP practices, value-added services and extension into prescription products.

Having filed DMFs for metformin (COMPRESSO MF 95P) and Paracetamol (COMPRESSO PAP 90 CPF) DC granules with USFDA and Canadian drug authorities, the Company is now preparing for the first ANDA audit for the DMFs filed by mid 2006. The Company is looking forward to the qualification and start-up of its new finished dosage facility as well as the new R&D facility and extensive vendor audits. As a step forward, the Company is also planning to file DMFs for ibuprofen and other DC grades in US.

In view of this, I can therefore assure stakeholders that Granules will leverage its existing position to grow in a sustainable way over the coming years.



# Operations PHARMACEUTICAL FORMULATION INTERMEDIATES

Review by Dr B R Reddy

Installed capacity	: 8400 TPA
Plants	: Jeedimetla and Gagillapur
2004-5 production	: 3838 MT
Gagillapur capacity utilisation	: 42 per cent
Jeedimetla capacity utilisation	: 69 per cent
Turnover 2004-5	: Rs. 83.07 cr
Proportion of overall revenue	: 62 per cent

**Performance:** During 2004-5, the Company manufactured about 3838 tonnes of PFI, generating a revenue of Rs. 83.07 cr, and produced about 107 millions of tablets for export. The Company expects to enhance the utilisation of the Gagillapur unit to in excess of 60 per cent by the end of the current financial year as initial samples turn into confirmed orders.

**Certifications:** The Company recognises the critical role of certifications in widening the market and customer mix. In view of this, both PFI plants at Granules are benchmarked to GMP standards, receiving regulatory approvals from various international agencies. The Company's regulatory strength is reflected in the fact that it received no adverse remarks during plant inspection and audit by the international certification agencies, a reflection of the completeness of preparation by the Company and related strengths in this area. As a confidence-enhancing initiative, the Company's plants were also successfully audited by reputed global customers like Aventis and Perrigo.

**Efficiencies:** To strengthen efficiencies, manufacturing discipline and process re-engineering is a must. In this direction all our actions are guided by exhaustive standard operating procedures (SOPs) - reviewed and revised periodically should the need arise - which cover functions like vendor selection, raw material selection, packaging and finished goods dispatch.

A reduction in process time without affecting the validated product parameters is another initiative: this effort yielded a 15 per cent improvement in the output of Paracetamol-based products; besides, campaign production planning in these products resulted in a daily output of 12 MT or almost 100 per cent of the Company's installed capacity for the product.

Similarly, process cycle time was shrunk through the implementation of sound production practices, lot-to-lot process planning and a reduction in the cycle time for material conveyance. Besides, plant downtime, necessitated by cleaning following a switch in the manufactured product, was also reduced.

The Company strengthened productivity by 12 per cent through employee training and expects to report another 8 per cent improvement in 2005-6.

**Product mix:** To de-risk the Company's dependence on a few products - the top 10 products manufactured by the Company account for 80 per cent of volumes - the R&D team is working on the development of new prescription products (two already introduced in 2005-6). As more products are evaluated and approved by customers, the Company expects to improve its capacity utilisation and the margins in the coming years.

To strengthen value-addition, the Company is extending into the manufacture of tablets for its customers through a proposed state-of-the-art finished dosages facility with an installed capacity of six billion tablets per annum. The plant, with the capability to compress, coat and pack different tablet types, will be guided by the quality systems implemented in the PFI plant.





# Operations ACTIVE PHARMACEUTICAL INGREDIENTS

Review by Mr. G V R Nagesh

Installed capacity	: 4241.60 TPA
Manufacturing plants	: Jeedimetla and Bonthapally (Paracetamol)
2004-5 production	: 3848 MT
Capacity utilisation	: 83 per cent
Turnover 2004-5	: Rs. 50.93 cr
Proportion of overall revenue	: 38 per cent



**Performance:** During the year under review, the Company manufactured 3848 tons of APIs, generating Rs. 50.93 cr in revenues. It generated about 2808 MT of API from the Bonthapally plant, achieving a capacity utilisation of 78 per cent, while the Jeedimetla plant operated at a capacity utilisation of 100 per cent.

**Certifications:** Both the Company's API plants are benchmarked to the GMP standards, having received regulatory approvals from various international agencies. The Company's plants were also successfully audited by major customers like Berlin Chemie, Ranbaxy, Pfizer, Aventis and CIPLA for paracetamol, Cadila Health Care for methocarbamol and Astra Zeneca and Procter & Gamble for guaifenesin. During the year under review, the Company successfully completed cleaning and process validations for certain other products.

**Product filing:** The Company submitted around 25 DMFs including guaifenesin Rev. 2, metformin HCl. Rev. 1, methocarbamol (new submission for US), paracetamol DMF for the Russian authorities; besides, around 18 technical packages were submitted to various customers.

**Productivity:** Product competitiveness can indeed be enhanced through increased productivity. In view of this, the

Company invested in a number of process re-engineering initiatives that significantly enhanced product productivity. The Company also enhanced efficiency through the following initiatives:

- Conducted cGMP training programs for employees.
- Assurance in the implementation of systems consistency through regular internal/ online audits.
- Minimised waste through the effective utilisation of resources like manpower, equipment and utilities.
- Effective implementation of preventive maintenance resulting in no major breakdowns of manufacturing/QC equipment.
- Regular monitoring of operations and motivation to concerned people on critical operations.
- Effective planning of lot-to-lot process.
- Enhanced awareness in good house keeping practices.

**Expansion:** The Company is setting up a 8000 TPA API plant for paracetamol at Bonthapally benchmarked with international standards. This plant, scheduled to be commissioned by January 2006, will cater to enhanced internal consumption besides improving product market share.