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Annual Report 2007-08

Vision

To become a large-scale consumer healthcare-focused service provider with a global presence and infrastructure to support strong partnerships with industry leaders.

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Disclaimer

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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Strong rupee. Financial upheaval. Uncertain business sentiment. Delayed commercialisation of facilities. Staggered benefits from our Ibuprofen facility in China.

A combination of these business realities translated into a challenging 2007-08 for Granules India Limited.



Despite this daunting environment, Granules India Limited grew its topline by 15.31% and EBIDTA by 2.40%, reflecting its competitive industry position.

Consolidate capacities

At Granules, we have consistently invested in our business across more than two decades of our existence. These investments have been made in scale, spread and sophistication, with the singular objective of strengthening our competitive industry position.

In the last five years, we invested in scale across the entire pharmaceutical value chain – from active pharmaceutical ingredients at one end to pharmaceutical formulation intermediates and finished dosages at the other – with the primary objective to graduate Granules from a product supplier into a solutions provider; from a vendor into a partner.

More specifically, these investments in people, technology, processes and infrastructure were made to address the large generics opportunity coming out of the global regulated markets. These investments have had the desired result. There has been a growing respect for our brand, translating into growing customer accretion on the one hand and enduring customer relationships on the other.

The time has now arrived for Granules to leverage the full benefit of its investments and graduate into a higher industry league. While the Company's API and PFI businesses have grown in terms of volume and customer quality, the FD business shows an attractive potential of growing rapidly from its nascent position.





▶ 2003

High-volume 7,200 TPA

PFI facility at Gagillapur

▶ 1985

Dedicated Acetaminophen facility at Bonthapally as Triton Laboratories

▶ 2005

New greenfield Acetaminophen facility at Bonthapally of 8,000 MTPA demolishing the old plant

1990

Multi-active facility at Jeedimetla

▶ 2006

Joint venture with Hubei Biocause, China

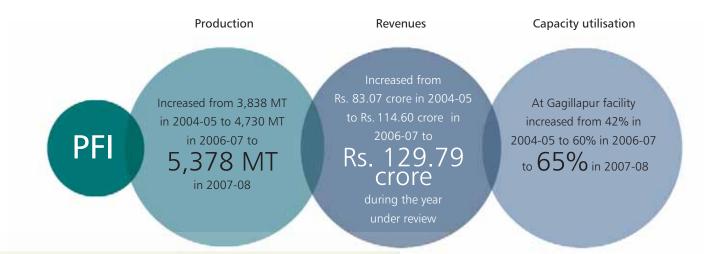
▶ 1993

Small volume PFI facility at Jeedimetla

▶ 2007

Finished dosage facility at Gagillapur

Growing API and PFI businesses



API Increased from 3,848 TPA in 2004-05 to 5,966 TPA in 2006-07 to 7,116 MT in 2007-08

Increased from
Rs. 50.93 crores in 2004-05 to
Rs. 70.02 crores in 2006-07
to Rs. 84.32
Crores
during the

Total
capacity utilisation
at 83% in 2004-05
(when installed capacity was
4,241.60 TPA); at 45% in 2006-07
(when installed capacity was
13,351 TPA); increased to
73% in 2007-08 (when installed capacity was
9,751 TPA)

At Granules, we expect our growth to accelerate for an important reason. The 6-billion tablet capacity of our FD facility with a potential to double to 12-billion tablets annually was commercialised in September 2008. This expansion has the potential to add considerably to our topline and bottomline beginning 2008-09, with full benefits expected from 2009-10 onwards.

The FD facility has been inspected and approved by Eu GMP, preparing it to cater to the growing demands of the European

market. Two of our FD products – ibuprofen and metformin – received approvals from TPD (Canada) in 2008. Products for the US market are being developed; the Company filed ANDAs for two products which, once approved, will facilitate a US entry within the formulations segment.

As these FD developments translate into growing revenues, we expect to enhance attractive value for our customers and shareholders.

Enhance market presence

Even as Granules is an Indian pharmaceutical company (headquartered in Hyderabad), it enjoys a dispersed global presence.

Three of the Company's manufacturing facilities are located in and around Hyderabad; it extended its manufacturing presence to China in 2007 through a joint venture with Hubei Biocause Heilen Pharmaceutical Co. Ltd., the world's fourth largest ibuprofen manufacturer and exporter. In doing so, Granules extended its presence to one of the most competitive API manufacturing geographies in the world.

Having invested significantly in capacity creation over the last five years, the Company is finding new markets through proactive business development. The result is a presence across 55 countries and over 300 customers. In 2007-08, exports contributed 74% to revenues. Nearly 67% of revenues were derived from the key markets of the US, Europe and Latin America, a 209-bps increase over the previous year.

Granules is strengthening its geographic presence through an entry into new markets on the one hand, and penetrating deeper into the existing ones on the other. The Company's

Geographic break-up of revenues from key markets in 2007-08 (in %)



strategy is to extend its presence from non-regulated markets to the regulated ones and strengthen its portfolio quality through an enhanced contribution from branded customers. The Company's investment in China will enhance competitiveness and facilitate a faster access to the high-margin regulated US and European markets.

Granules focused on customer proximity through a proactive US marketing infrastructure created as early as 2003. The Company is now leveraging this infrastructure and a five-member experienced team to enhance North American penetration, especially Canada and the US. In 2007-08, the North American market at Rs. 71.92 crore accounted for almost 33% of the Company's overall revenues (37% in 2006-07).

Correspondingly, Granules also created a marketing infrastructure in the UK and Colombia, with the objective to penetrate the regulated markets of Europe and the high-growth markets of Latin America. The latter opportunity is particularly attractive for the following reasons:

- The Latin American pharmaceutical market is estimated at US\$50 billion and is rapidly growing.
- The eight key pharmaceutical markets of Argentina, Brazil, Chile, Colombia, Cuba, Mexico, Peru and Venezuela will represent a value of US\$80 billion at 2013 retail realisations.
- These eight countries represent a market of 474 million individuals, aggregating a GDP of US\$3.4 trillion (2008) with unfulfilled demand driving public drug expenditure.
- Revenues from Latin America at Rs. 48.74 crore contributed 22% to total revenues compared with 23% in the previous year.

Revenue contribution from Europe increased from 5.33% in 2006-07 to 12.48% in 2007-08. The year under review saw Granules successfully complete six site transfer projects for the European markets, which, when commercialised, will significantly increase revenues from the continent.



Granules is also expanding its presence in Russia, the largest pharmaceutical market in Central and Eastern Europe with an estimated size of US\$11.7 billion in final 2007 consumer prices, representing a 20% year-on-year growth (Source: BMI). Around three quarters of the market is supplied by imports, as the domestic production of innovative pharmaceuticals is negligible and foreign manufacturers are more competently placed to meet the growing demand for expensive drugs.

The result is that over the next couple of years, the Company will enhance its presence in a relatively underpenetrated Eastern Europe and Russia and aggressively market products in North America, Latin America and Europe.





The next two years at Granules will be ones of investment consolidation, helping us reap the benefits of our expanded capacities across businesses and adding to shareholder value.

Mr. C. Krishna Prasad, Managing Director, analyses the Company's performance and focuses on the future.

Dear share holders,

It would be reasonable for every exporter to expect a reasonable return on employed capital.

The year 2007-08 was one that challenged this assumption for an important reason: an unprecedented appreciation in the Indian rupee by more than 10% eroded almost 7% of our topline, leaving us with a declining room to cover our fixed costs. In a business where we derived almost 74% of our revenues from international markets, we rightsized our product mix with speed. We selected to retain those products where we could generate reasonable margins or effect price increases. As it turned out, this conscious call to relinquish a major part of our PFI business protected our brand and return on employed capital.

Setbacks

There was another source of disappointment. A contract with one of our largest US customers for the purchase of OTC

Monograph finished dosages from our new plant could not be completed due to issues at the customer end. The annulment of this contract, which could have resulted in 50% capacity utilisation and correspondingly positive financial implications, delayed the commercialisation of our formulations facility by almost 18 months and staggered our payback.

Besides, there were adverse industry developments in China, marked by a rising currency and withdrawal of subsidies, which translated into a lower-than-expected return from our ibuprofen plant in that country. A delay in the production stabilisation of our new paracetamol plant at Bonthapally delayed returns. As against the nameplate capacity of 8,000 MT annually, we were able to achieve a capacity of only 32% in 2007 and 72% in 2008.

The cumulative impact of these factors was an inability to achieve our targeted sales of Rs. 270 crore and a bottomline

of Rs. 14.85 crore (PAT) for the year ended June 2007, and sales of Rs. 490 crore and a bottomline of Rs. 22 crore in 2007-08. Compounding this aberration was an unprecedented decline in the BSE Sensex by 48% between July 2007 and June 2008, and more than 75% between December 2007 and June 2008, affecting overall shareholder returns.

Despite the challenges, our revenues increased from Rs. 188.16 crore in 2006-07 to Rs. 214.83 crore, while our EBIDTA increased from Rs. 33.69 crore to Rs. 34.50 crore. However, there was a decline in our profits on account of depreciation provided on the new manufacturing plants as well as the adverse industry realities. Our net profit declined by 9.74% to Rs. 9.13 crore in 2007-08.

Competitive edge

Over the last five years, we have strengthened our business through consistent investments in scale and integration. The result is that we are now one of the most vertically integrated outsourcing partners within the pharmaceutical industry, with a comprehensive range of contract services from preformulations, analytical and formulations development, scale-up and high-volume commercial manufacturing as well as regulatory support and approvals. The result is that today, we can take a client's product from the earliest development stage all the way to the market.

Besides integration, we invested in scale with the objective to protect our margins at one end and offer unbeatable value (integrated services with low costs) through the following initiatives:

- Creation of the world's largest standalone 7,200-TPA PFI capacity, completely automated plant with the world's largest batch size of 6,000 kgs
- Creation of 8,000-TPA paracetamol API plant, helping us meet 8% of the 1,00,000-TPA global paracetamol market

• Creation of a multiple finished dosage facility with an installed capacity of 6 billion tablets annually (scalable to 12 billion tablets annually), making us one of the few in our industry with capabilities to meet the large volume requirements of global pharmaceutical majors.

Patience

Even as we invested in fresh capacity creation, our fresh investments needed a reasonable lead time before yielding results, usually longer than in most businesses, on account of extensive regulatory requirements. So while our API and PFI businesses matured and started yielding results, our formulations business was relatively new. The formulations facility was ready to be commissioned last year, but commercial operations began only in September 2008 on account of customer validations, site transfer approvals, regulatory inspections and approvals before the product could be marketed in the US, Canada and Europe.

During the year under review, our formulations plant was approved by Infarmed (EU), which will enable us to penetrate Europe with our finished dosage portfolio. We completed site transfer projects for key formulations product – paracetamol – from the European markets, which will now go into commercial supplies. Ibuprofen and metformin received site transfer approvals from TPD (Canada) for commercial supplies at our Gagillapur facility. Six different products targeted at the Canadian markets are under development, including combination and single products. We filed ANDAs for ibuprofen and metformin, which are at an advanced stage of review and, once approved, will be marketed in the US.

Over the last few years, we built an efficient US marketing and distribution infrastructure through our US subsidiary. I am pleased to state that the investment has started reaping benefits; the subsidiary turned profitable in the first quarter of the current year and, going ahead, we expect to enhance our

market share in the US and Canada. Our alliance with Matchland provides us with a key customer in the OTC segment in the Australian market. The site transfer projects will help us increase our finished dosage sales in Europe. We also strengthened our presence in Latin America through a marketing office in Colombia, the fifth largest in the region.

Having reinforced capacities and scale, our enhanced focus on business development – creating new markets and strengthening the existing ones – will help us effectively utilise our capacities. The benefits of our investments in finished dosages will start accruing from the current year and will be fully visible from 2009-10 onwards.

Way forward

Going ahead, we expect to increase our contract manufacturing services for different generic and branded products. With regulated markets becoming competitive and respective governments looking at healthcare cost reduction, we expect that our improved efficiencies, economies of scale, internationally benchmarked facilities and presence across the pharma value chain will result in large customer accretion.

Granules is attractively position to make this a reality: it is one of the few global companies to be vertically integrated in the dosages it specialises in and where efficiencies are driven by high capacities at all stages of operations like API, PFI and finished dosages. The result: a distinctive competitive edge within the contract manufacturing space.

We will continue to focus on the OTC segment, which provides immense outsourcing opportunities, without losing sight of the prescription segment. We are also focussing on value addition in the formulations segment, utilising the existing infrastructure to offer customers low-volume, high-margin niche products that are difficult to manufacture. We are also in discussions with key MNC customers for supply contract agreements, which will enhance our finished dosage volumes. We are extending to service the needs of key

multinational customers, moving from generic to high-margin branded customers.

The next two years at Granules will be ones of investment consolidation, helping us reap the benefits of our expanded capacities across businesses and adding to shareholder value. Our focus on Europe will progressively counter a dependence on the US and corresponding dollar depreciation. While commercial shipments for some products developed under site transfer of dossiers of the multinational companies have already begun, we expect to commercialise one formulation product every four months.

Currently, the currency exchange value is also favourable and we have entered into medium to long-term contracts with some key customers, based on pricing linked to our key raw materials and currency, protecting ourselves from a probable loss due to unexpected currency fluctuations.

Finally, I am happy to state that the anticipated numbers in terms of topline and bottomline are becoming a reality with a lag of 18 months. The paracetamol and PFI plants are working close to their respective nameplate capacities covered by sales contracts for a major part of the output. This, coupled with the fact that the finished dosage plant will also commercialise products at a steady rate, makes me optimistic of achieving a 60% revenue growth in the current financial year.

Yours sincerely,

C. Krishna Prasad

Managing Director

Management discussion and analysis

Global overview

Global pharma sales grew 6.4% in 2007 to a record US\$712 billion (Source: IMS Health). The US (40.2% market share) reported its slowest growth (3.8%) since 1961, contributing a mere 25% to industrial growth. The sluggish growth was a result of patent expirations, generic products growth, fewer and narrowly focused novel medications, safety issues and dearth of new products.

On the other hand, Europe recorded revenues of US\$221.6-billion, Russia and Turkey being the largest contributors with 20.2% and 17.2% share, respectively. Japan grew 3.6% to US\$65.2 billion. The rest of the world, including Asia, Australia and New Zealand, reported a buoyant growth of 13.3% to US\$78 billion, contributing 11% of the global market. This was followed by Latin America, up 11.6% to US\$11.1 billion.





Global sales (US\$ billion)

	2004	2005	2006	2007
Total world market	560	605	649	712
Growth	8%	7.3%	7.1%	6.4%

Source: IMS Health Market Prognosis (include IMS audited and unaudited market)

In 2008, drugs estimated at around US\$20 billion are expected to lose their patent protection. Leading products are gradually losing their share in major markets, triggering a 15% generic sale growth to more than US\$70 billion (value).

Indian overview

The highly fragmented Indian pharmaceutical industry accounts for about 1% of the world pharmaceutical industry by value and 8% by volume. It comprises about 24,000 players (around 330 in the organised sector) and is worth around US\$8 billion. The top 10 players constitute more than a third of the market. Revenues generated by this segment grew at an average 10% over five years, following enhanced awareness, penetration and affordability. The anti-bacterial CNS and diabetes segments registered a 15-20% annual growth.

Domestic pharmaceutical companies cater to almost the whole of the country's formulations demand and nearly 70% of the country's bulk drugs demand. Exports constitute nearly 40% of production (formulations – 55% and bulk drugs – 45% in the export pie). The Pharmaceutical Export Promotion Council indicates that exports in 2007-08 stood at US\$ 6.68 billion (US\$ 5.73 billion in 2006-07). The industry ranks 17th in the export value of bulk actives and dosages.



CRAMS opportunity

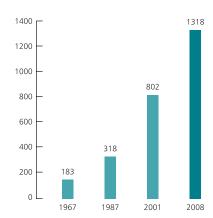
Global peers are facing mounting R&D costs, declining productivity in new drug discovery, patent expirations and declining profitability. In this demanding environment, Contract Research and Manufacturing Services (CRAMS) appears a relevant solution, which makes it possible to contract non-core and uneconomical research and manufacturing services to third parties in low-cost destinations like China and India.

Escalating cost pressures: Over the last three decades, the cost per New Molecule Entity (NME) increased significantly, following growing regulatory pressures reflected in lengthy clinical studies. This represented the key reason behind offshoring to low-cost destinations like India and China.

Declining R&D productivity: Despite colossal R&D spends, new drug approvals by the USFDA recorded a significant slump. The reduced number of blockbuster drugs with mounting R&D costs is driving global pharma companies to outsource R&D to maintain margins.

Increasing genericisation: In recent years, innovative pharma companies faced a challenge from their large generic counterparts, causing several blockbuster drugs to lose patent protection due to successful patent challenges. Most existing drugs are also confronting generic competition. The rising generics thrust over branded formulations by developed economies poses a concern for innovators, affecting profitability.

Cost to develop a drug (US\$ mn)



(Source: PhRMA Profile 2008)

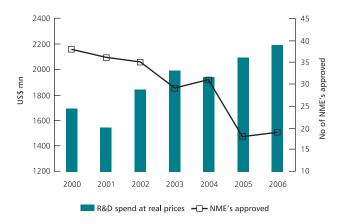
Globally, the CRAMS business is estimated at US\$20 billion and expected to reach US\$31 billion by 2010. Currently, India accounts for a mere 3% of the global CRAMS market but this is expected to grow to 10% in a decade. The CRAMS segment in India is estimated to have earned revenues of approximately US\$895 million in 2006, likely to reach nearly US\$6.6 billion by 2013.

Contract research: Contract research organisations provide services that comprise drug discovery, new product development, formulations, pre-clinical and clinical trial management spanning phases I to IV. Outsourcing volumes generally grow from grams to kilograms as NCE progresses through various development stages. India and China are preferred CRO destinations in Asia, the former poised to reach US\$2 billion by 2010 (Source: Frost and Sullivan).

Contract manufacturing: Following NCE commercialisation, contract manufacturing (CMO) involves the supply of large quantities. India is competently placed to capitalise on this through its rich experience in the manufacture of APIs and other intermediates around a 40% lower cost structure than that of the developed markets. This could be either for onpatent or off-patent molecules, leading small and medium units to expand capacities. The Boston Consulting Group estimates that the contract manufacturing market for global companies in India could touch US\$900 million by 2010.

The Indian advantage

Decline in R&D productivity over the years

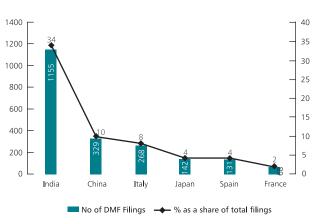


(Source: PhRMA Profile 2008, USFDA)

India has established itself as one of the most preferred pharma outsourcing destinations for the following reasons:

- Highest number of USFDA-approved plants in India: India has the maximum number of USFDA-approved plants (over 75) outside the US. Increasing yearly approvals are catalysing a widened global presence on the back of large volumes, superior quality and technological know-how.
- India tops global DMF and ANDA filings: India has been a forerunner in DMF and ANDA filings, with approximately 35% and 25% shares, respectively. The last three years witnessed several second-and-third tier pharma companies aggressively scaling their ANDA/DMF filings in the US.
- Low manufacturing cost: The manufacturing cost in India is 40% lower than that in developed markets, without a corresponding quality compromise. Even labour cost is one seventh of that in the US, an unbeatable USP.
- Rich talent pool: India possesses competent physicians and technical personnel with dependable English speaking skills. With chemists and engineering graduates increasing annually, India enjoys six times the number of trained chemists in the US for a tenth of the cost.
- Superior infrastructure: An enlarging global CRAMS opportunity catalysed massive pharmaceutical industry expansion in India, facilitated by superior telecom and IT infrastructure, enabling rapid and proactive response to global needs.

Country-wise DMF filings (June 2000-07)



(Source: USFDA, Crisil)

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Budget measures

- 15% increase in health sector allocation
- Increase in the allocation to the National Rural Health Mission to Rs. 12,050 crore
- Provision of Rs. 993 crore to the National Aids Control Programme
- Rs. 1,042 crore allocation for polio eradication with a focus on high-risk Uttar Pradesh and Bihar districts
- Reduction in customs duty from 10% to 5% on certain specified life-saving and bulk drugs
- Decline in excise duty on all goods produced, from 16% to 8%
- Weighted deduction of 125% on payment to companies engaged in R&D

Budget impact

- Increased allocation, an indication of infrastructure ramp-up for greater access to quality healthcare by a majority of the population
- Excise reduction to boost corporate profitability (duty paid on MRP)
- Customs duty reduction on life-saving drugs to provide an edge to companies catering to these segments
- Weighted deduction, a boost for companies involved in R&D

SCOT analysis of the Indian pharmaceutical industry

Strengths

- Low production cost
- Large installed capacity
- Efficient technologies for a large number of generics
- Large technical manpower
- Liberalised government policies
- High purity standards
- World-class laboratories

Challenges

- Non-availability of major intermediaries for bulk
 drugs
- Low 1% share of world production corresponding to 16.1% of the world's population
- Nascent biotechnology research and New Drug Discovery Systems
- Relative inexperience in international trade

Opportunities

- Ageing global population
- Increasing incomes
- Growing health awareness and attention
- New therapy approaches
- Increasing awareness for soft medication (OTC drugs)
- Growing use of generic drugs
- Globalisation
- Emerging markets
- Attractive export potential
- Increasing contract manufacturing focus

Threats

- Rising healthcare cost
- Stringent registration procedures
- High entry cost in newer markets
- High cost of sales and marketing
- Growing competition in generic products
- Switch-over from process to product patents

Our presence

Headquartered in Hyderabad (India), Granules' manufacturing facilities are located on the outskirts at Jeedimetla, Bonthapally and Gagillapur. The Company is an integrated pharmaceutical player with API, PFI and formulations manufacturing capabilities. The Company also commissioned an ibuprofen manufacturing facility in China under a joint

venture with Hubei Biocause Heilen Pharmaceutical Co. Ltd.

The Company enjoys a 55-country footprint, leveraging regulatory service expertise and offering a one-stop global outsourcing solution. It also has a 100% US subsidiary to specially market in that region.





Type of facility	Location	Capacity	Approval from
API plant (Multi-product)	Jeedimetla	Metformin HCI: 960 MTPA Methocarbamol: 96 MTPA Guaifenesin: 640 MTPA Phenazopyridine HCI: 48 MTPA	USFDA, KFDA, TGA, EDQM
API – (Paracetamol/Acetaminophen)	Bonthapally	8,000 MTPA	USFDA, WHO GMP, EDQM, Infarmed (EU)
PFI – (Multiple small volume facility)	Jeedimetla	1,200 MTPA	USFDA, Australian TGA, German HA
PFI	Gagillapur	7,200 MTPA	USFDA, German HA, Australian TGA
Formulations	Gagillapur	6 billion tablets per annum (scalable to 12 billion tablets per annum)	Infarmed (EU), USFDA
API – (Ibuprofen)	Wuhan, China	3,600 MTPA	USFDA, EDQM, TPD – Canada, MCC, Russian health authorities

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Operational review

API division

Overview

The Company's API facilities are located at Jeedimetla and Bonthapally. The Jeedimetla unit manufactures APIs like Metformin, Methocarbamol, Guaifenesin and Phenazopyridine, whereas the Bonthapally unit manufactures APIs like Paracetamol or Acetaminophen.

Highlights, 2007-08

Proper preventive maintenance and production planning resulted in an improved performance during the year, which is reflected in the following:

- Achieved highest production of Metformin HCI (71,608 kgs in June 2008) at the Jeedimetla unit
- Recorded highest sales of 70,800 kgs for Metformin HCI
- Surpassed the 500 MT monthly production mark at Bonthapally unit
- Developed a process for fine crystal grade
- 76% and 73% capacity utilisation at the Jeedimetla and Bonthapally units, respectively

Initiatives

To enhance productivity, the Company modified the process of Phenazopyridine HCl by reducing the reaction process from three stages to 1.5 stage, resulting in cost reduction and improvement in cycle time. Overall, the Company could save a minimum of Rs. 1.24 crore annually.

PFI division

Overview

The Company's PFI facilities are located at Jeedimetla and Gagillapur. It manufactures combination PFIs using multiple APIs. The plants enjoy regulatory approvals from the major regulatory agencies like USFDA, Australian TGA, Canadian TPD and German HA.

Highlights, 2007-08

Thanks to reduced in-process drying time, the Company achieved the following during the year:

- Increased the production of 80 DPL from 9.6 MT to 10.8 MT daily
- 60% and 65% capacity utilisation at the Jeedimetla and Gagillapur units, respectively

- Commercialised Glucosamine products GLU 99 DE and Compresso GLU 80
- Commercialised the site transfer products like PAP 83.3 (Teva)
- Commercialised the IBU 66 S

Initiatives

To enhance productivity and future efficiencies, the Company has set up a new RMG module called Module A. Hence, it is now transferring some of its products from Module B to Module A for better results.

Formulations division

The Company commissioned its tablet facility at Gagillapur in October 2007 with an annual capacity of six billion tablets (scalable to 12 billion tablets annually). The plant enjoys state-of-the-art facilities, automated processes, robust infrastructure and excellent quality systems. It received approvals from TEVA, EuGMP, WHO, San Pharmaceuticals Ltd., Par Pharmaceuticals Ltd., ACTAVIS and A&A.

Highlights, 2007-08

- Despatch of around 300 million tablets
- Quality approvals of IQ, OQ and PQ for all tablet-block
 machines
- Successful regulatory audits of EuGMP and WHO
- Successful customary audits of TEVA, San Pharmaceuticals Ltd., Par Pharmaceuticals Ltd., ACTAVIS and A&A
- Commercialisation of scale-up batch, qualification batch and validation batch for Acetaminophen, Ibuprofen, Metformin and Paracetamol
- Scale-up and exhibit batches undertaken for 17 more products (including combination products)
- Plant utilisation of about 15-20%, covering scale-up and exhibit batches

Initiatives

The Company undertook the following initiatives to improve productivity and efficiencies:

- Conducted trials to increase compression machine speed through a continuous modification of some parameters
- Increased the solid content and spray rate to reduce coating time
- Trained technicians in daily operations, cleaning and troubleshooting

Raw material management

Granules is a 100% export oriented unit benefiting from duty-free import. It imports a majority of its raw materials from China (highest share), France, Germany, Taiwan, Korea, etc. to avail of price advantages.

The Company conducts raw material cost and quality checks through periodic audits. Since raw materials are sourced in large volumes, the Company can negotiate better. While identifying a new vendor, all quality standards are considered.

The following initiatives strengthened Granules' supply chain:

• Arriving at contracts with varying durations (quarterly, half-

yearly and annually)

- Strengthening relationships with dependable manufacturers
- Declining lead time, reducing inventories
- Tracking markets for proactive response

The Company reduced its lead time for high-volume materials by shipping on direct vessels, diminishing the voyage time without any cost increment. Result: Granules procured materials at a short notice; it increased the effective credit period and even reduced inventories.



Research and development

During 2007-08, the Company invested around Rs. 2 crore in R&D, focusing on technology development and transfer for OTC products, OTC ANDA products, rapid release gels and Rx ANDA products. Of 35 projects, development was completed for most, while others were at various development stages. As a result, three ANDAs were submitted, with eight ANDAs in the pipeline to be submitted before July 2009. About five products were commercialised for regular production in Canada, the US and Europe. The development of four rapid release gel formulations was completed and one was commercialised for the Canadian market.

Process capability enhancement of existing products also

figured on the agenda; the Company undertook several site transfer projects from global (the EU and the US) customers.

The Company will emphasize the launch of innovative finished dosage forms, increasing productivity in PFI and finished dosage manufacture, besides trimming production costs. Formulations R&D will focus on developing Rx ANDA products for global geographies, while API R&D will emphasize cost reduction and developing cost-effective technologies to commercialise new APIs. Supporting captive consumption for new PFIs and finished dosage forms will constitute the key criteria for selecting new API targets.

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