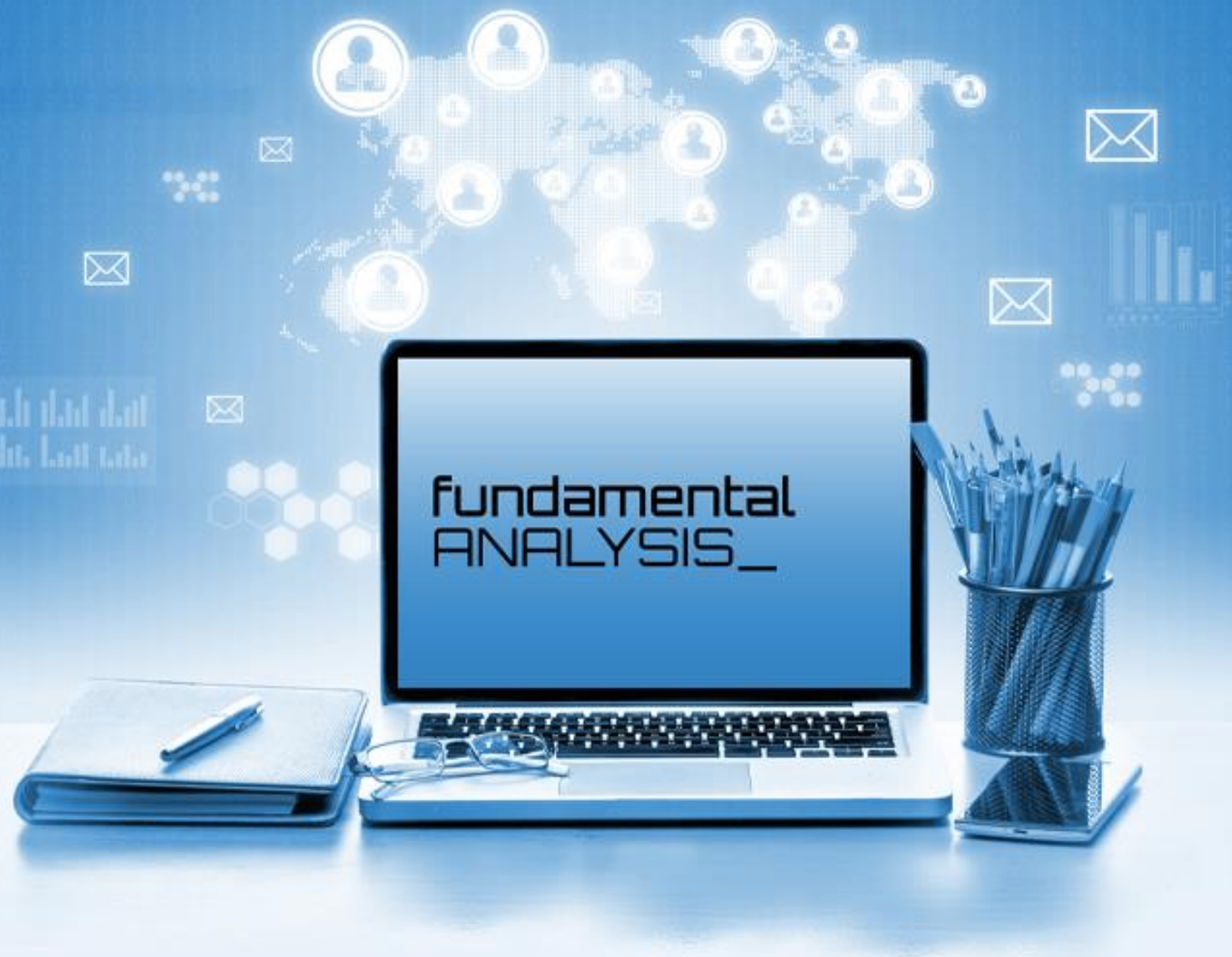
Stock Note

Granules India Ltd.

Jan 16, 2024



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Granules India Ltd.

Industry	LTP	Recommendation	Base Case Fair Value	Bull Case Fair Value	Time Horizon
Pharmaceuticals	Rs 430	Buy in the range of Rs 430-434 & add more on dips to Rs 384	Rs 470.5	Rs 507	2-3 quarters

HDFC Scrip Code	GRANULEQNR
BSE Code	532482
NSE Code	GRANULES
Bloomberg	GRAN IN
CMP Jan 15, 2024	430
Equity Capital (Rs cr)	24.2
Face Value (Rs)	1
Equity Share O/S (cr)	24.2
Market Cap (Rs cr)	10010
Book Value (Rs)	117
Avg. 52 Wk Volumes	2108098
52 Week High	426
52 Week Low	269

Share holding Pattern % (Dec, 2023)	
Promoters	41.96
Institutions	28.94
Non Institutions	29.1
Total	100.0

HDFCsec Retail research stock rating meter

for details about the ratings, refer at the end of the report

*** Refer at the end for explanation on Risk Ratings**

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Our Take:

Granules India Ltd. is a fully integrated pharmaceutical company having presence across API-PFI-FD value chain (Active Pharmaceutical Ingredients (API), Pharmaceutical Formulation Intermediates (PFI) and Finished Dosages (FD)). Granules has one of the largest PFI and single site FD facilities in the world and has the world's largest Paracetamol API facility. Granules has two research and Development (R&D) centers in Hyderabad and Virginia, alongside its existing R&D facilities in Pune and Pragathi Nagar (Hyderabad).

Exports now contribute over 94% of overall business. Company has progressively moved from being an API to a fully integrated player with dominant finished dosage sales. Company has very strong presence in the US market, driven growth trajectory built on scale, manufacturing excellence, focused execution, and cost leadership. It is also making good inroads within Europe and contribution from the region has been on an upward trend.

After robust numbers in FY21 led by highest ever gross margin of 57%, the company reported steep decline in FY22. However, the company reported steady numbers in FY23 and H1FY24. We expect strong numbers from H2FY24 led by new launches and healthy growth from existing molecules. Company has high dependency on few products, however it has reduced this gradually over the past three years.

In FY23, the company reported strong 20% growth in revenue along with margin improvement. Q1FY24 was impacted due to IT related issue, however overall performance remained strong in Q2FY24. Raw-material prices and freight costs are easing over the past few quarters. Measures taken to reduce dependence on China and initiating a price hike across customers would help it offset any concerns around China led API price increases. Commissioning of the MUPS block and a strong product pipeline across regions to support growth. However, we need to watch impact of recent unfavourable change in the product mix and expected rise in R&D spending coupled with increased finance and depreciation costs, along with continued price erosion in the formulations segment. Nevertheless, strong sales growth coupled with productivity measures should help it offset its impact partially over the medium term.

Company indicated for about 7 launches in H2FY24, which should drive further growth momentum in the US. Inventory build-up is largely to cater to US business. The project related to PAP is expected to be completed by FY25. Company spent Rs 180 crore on capex for H1FY24 and intends to spend Rs 400 crore in H2FY24. The backward integration of its core products (Paracetamol/Metformin) is also on track to improve overall profitability over the medium term. Its focus on enzyme and fermentation technology to build the pipeline of complex products in the regulated market will support overall growth over the next 12-18 months.

Valuation & Recommendation:

The company has been witnessing strong growth for its Formulation business, mainly in regulated markets like US and UK. H2FY24 is expected to witness signs of recovery, led by new product launches and volume growth driving strong sales growth coupled with productivity measures which would lead to decent earnings growth for the company in the medium term.

We estimate Revenue, EBITDA and PAT to grow at CAGR of 9.7%, 11.2% and 12% respectively, over FY23-26E. US business is expected to grow at robust pace led by steady base business, market share gains and new limited competition launches in the medium term. As most respiratory inhaler products are going to be limited competition, it will lead to sustainable margin expansion in the US. We feel investors can buy the stock in the range of Rs 430-434 and add more on dips to Rs 384 (13.25x Dec-25E EPS) for base case target of Rs 470.5 (16.25x Dec-25E EPS) and bull case target of Rs 507 (17.5x Dec-25E EPS) over the next 2-3 quarters.

Financial Summary

Particulars (Rs cr)	Q2FY24	Q2FY23	YoY (%)	Q1FY24	QoQ (%)	FY19	FY20	FY21	FY22	FY23	FY24E	FY25E	FY26E
Total Revenues	1189	1151	3.4	986	21	2,279	2,599	3,238	3,765	4,512	4,792	5,381	5,973
EBITDA	213	243	-12.4	137	56	384	525	855	722	914	920	1103	1261
Depreciation	53	44	19.3	49	6	106	137	152	159	184	208	231	249
Other Income	2	5	-68.8	0	275	27	37	27	18	14	16	19	23
Interest Cost	26	13	96.2	23	15	29	27	26	23	56	87	61	48
Tax	34	45	-25.2	18	93	89	116	155	145	171	165	215	256
PAT	102	145	-29.6	48	113	236	336	550	413	517	476	615	731
EPS (Rs)						9.3	13.2	22.2	16.6	21.4	19.6	25.4	30.2
RoE (%)						16.7	19.9	27.4	17.3	19.1	15.5	17.1	17.2
P/E (x)						46.1	32.5	19.3	25.8	20.1	21.8	16.9	14.2
EV/EBITDA (x)						29.6	21.7	13.3	15.8	12.5	12.4	10.3	9.0

(Source: Company, HDFC sec)

Q2FY24 and H1FY24 result update

Revenue for the quarter grew 3.4% YoY at Rs 1189.4cr. Gross margin (GM) expanded 190bps YoY to 51.7% due to change in the segmental mix as well as product mix. However, EBITDA margin slipped 320bps YoY at 17.9% due to an increase in employee costs/other expenses. Net profit declined 29.5% YoY at Rs 102.2cr due to higher finance costs and lower other income. Finance costs increased 96% YoY at Rs 26cr. Other Income declined 69% YoY at Rs 1.5cr.

API sales declined 9% YoY at Rs 302cr. Pharma formulation intermediates (PFI) sales were down 38% at Rs 146cr. Formulation sales increased 27% YoY at Rs 742cr. EPS for the quarter stood at Rs 4.22 and it stood at Rs 6.2 for H1 FY24.

11% YoY growth in US sales was largely due to increased business from existing products. The price erosion has impacted business in EU for the quarter.

Employee costs were higher in H1FY24 due to the commissioning of MUPS block and Virginia packaging facility.

Volume growth on YoY basis was higher as compared to value growth. Sales in the US region grew well, partially offset by decline in the LatAm and European regions. API, Pharmaceutical Formulation Intermediates (PFI), and Formulations contributed to 25%, 12%, and 62% of revenue from operations respectively for Q2FY24.

In Q1FY24, overall business got impacted due to IT incident. This had a major effect on the business due to significant changes in IT systems and the time needed for meeting the regulatory expectations, qualifications, recertifications, and fine-tuning of quality and production systems.

In addition to the resolution of intermittent issues, Granules has operationalized MUPS block as well as packaging facility at Virginia.

Further, the investment remains on track at Genome Valley, with phase II expected to be completed by May-24, adding 2.5 billion capacity. It is implementing efforts towards capacity addition and backward integration, and is enhancing product offerings for the regulated market, including some niche launches.

With respect to CZRO update, third-party technical feasibility study report is received and final discussions with Greenko are in progress.

In H1FY24, overall sales stood flat YoY at Rs 2175cr as IT security issue impacted production/sales activities. Finance costs surged 140% YoY at Rs 48cr. Net profit declined 45% YoY at Rs 150cr.
In H1FY24, the company reported 11% YoY growth in the US business to Rs 1401cr, largely due to volume growth. However, EU revenue declined 2% to Rs 454cr on account of price erosion, slightly offset by volume growth.

In H1FY24, the company launched four products in the US and one in the UK.

Further, to enhance its revenue share from the regulated market, it plans to launch seven products in the US, two products each in UK, EU and South Africa in H2FY24.

Its focus on enzyme and fermentation technology to build the pipeline of complex products in the regulated market will support overall growth over the next 12-18 months.

Concall Highlights

- As per IMS numbers, the company has gained market share quite fast for most of major products.
- Capex guidance of Rs 700 crore for FY24 remains intact. The company has already spent Rs 180 crore in H1FY24 and expects to invest Rs 400 crore in H2FY24. Company plans to file 10-12 ANDA in FY24.
- Management has identified and finalized two plants: One at Vizag (12 acres) and another at Kakinada (100 acres).
- PAP Projection is expected to be completed by the end of FY25.
- Project work of phase 2 at Kakinada is expected to start in FY25.
- Ongoing collaboration with multiple partners on technological know-how for molecules envisaged under CZRO for Kakinada.
- Some of the launches of the approved products in the US and other geographies were delayed due to the IT incident and will be launched in the coming quarters. This will aid revenue growth and profitability.
- Granules has approval for 59 products and 2 tentatively approved ANDA, 5 European dossiers in the UK, 6 in Canada, and 3 in other regions, a total of 75 dossiers approved and 21 global dossiers to be approved.
- Granules has a total of 33 US DMFs, 24 CEPs, 5 EDMFs, 8 KDMFs, 4 Canadian DMFs, 4 China DMFs, 2 Japanese DMFs and 50 filed across several regions.
- There are about 41 products which are under various stages of development at Granules integrated product development center All these products are scheduled to be filed in FY24E and FY25E.
- The technology development team has made significant progress on the application of Biocatalysis to three products, of which two products have completed the pilot scale and commercial production at plants, and the third molecule has completed optimizations in the lab These 3 products can give significant and sustainable advantage for Granules when they are commercialized.
- During the quarter, ANVISA audit at the Gagillapur formulations plant was completed with zero critical observations and compliance with the guidance of cGMP for the Bonthapally factory was received.
- Health Canada audit at Jeedimetla API plant was successfully completed with zero critical observations.
- CZRO (Greenko) update - Third-Party Technical Feasibility Report received is under the final review; discussion with AM Green (Greenko) is in progress.

- Granules' new packaging site in Virginia, US, is fully operational but is yet to stabilize, contributing to higher manpower costs as of sales. Overall R&D manpower has also gone up 50% YoY.
- At CZRO, the company is putting up a pilot plant for DCDA and a small commercial plant for PAP at the Vizag plant Granules has received the technical feasibility report and is under final review and discussions with AM Green, which is part of Greenko on the project planning for the Kakinada site, which will be the main facility for CZRO The project work at Kakinada, which will be the main facility for CZRO, is planned to start during FY25E.
- Granules has started work on the backward integration of 10 additional critical products after Paracetamol and Metformin, which would give desired results in the next 3-4 quarters.
- R&D spend for the quarter was at Rs 49.6 crore vs. Rs 24.6 crore in Q2FY23 and Rs 41.3 crore in Q1FY24.
- Price erosion was partially offset by significant volume growth in North America business. Europe sales declined due to increased price erosion.
- Volume decline continued in Latin America, primarily on account of inventory correction by customers in these regions coupled with demand challenges.
- Decline in the API segment on YoY basis was led primarily by reduction in the prices of the key products, which were reduced in line with the decline in key raw-material prices (no impact on margins).
- Share of the PFI business has reduced YoY, as more customers are converting into FD from PFI, coupled with correction in inventories in LatAm markets.
- FD volumes increased significantly in the US across major products.
- Company launched four products in the US and one product in the UK in H1FY24 and expects to launch about seven products in the US, two products in South Africa, two products in the UK and two products in Europe in H2FY24.
- Granules imports DCDA and PAP from China. Earlier, there was shortage of PAP in China but the situation has normalised. Indian manufacturers also started manufacturing PAP while other international manufacturers came up. For DCDA, they had suppliers from Europe but now energy costs have gone up. Hence, Granules is buying it from China. Company has set up DCDA pilot plant having 8000 MT capacity, likely operational in early FY25.
- Formulation sales were the major contributors for growth in the US market. Most of the growth was from existing formulation products and the rest from new launches. Formulation sales increased mainly due to shift of most of the PFI customers towards FD.
- Going forward, management believes FD will grow and PFI and API growth will be subdued.
- Net debt during the quarter stood at Rs 990cr. Debt is in foreign currency, Rs 150cr is long-term debt, and the rest is short-term working capital debt.

- R&D expense during the quarter was at Rs. 49.6cr. Staff expenses increased due to manpower hired as MUPs blocks and packaging plant were fully operational, but there was some delay in launches. By the end of Q4FY24, the plant is expected to generate revenue and cover higher manpower costs.
- Launch of Metoprolol has been delayed. It is expected to be launched by the end of Q3FY24, which would drive US sales further.
- Raw-material cost benefit and cost improvement benefit were largely offset by product mix and price erosion.
- Inventory built-up was largely due to new launches and to serve US market. No inventory write-off issues seen in H2FY24.
- Product mix for 2 to 3 years down the line will be in the same range, formulation contribution will be beyond 60%.
- Management highlighted that legacy products will continue to grow, while new products will be more profitable but volumes may not be at the same level.
- The company has already received PLI approval for 8000 TPA DCDA projects and management plans to get approval beyond 8000 TPA (can be applied to receive approval for 30,000 TPA).

IT incident update

- Production and sales restored to normalcy. The company has enhanced its security environment.
- The company initiated continuous improvement process for systems and security are put in place.
- Launches in the US and other geographies were delayed and are expected in H2FY24, which will
- contribute to higher revenue and profitability.

Facility inspection update

- ANVISA audit completed for Gagillapur formulations plant and Bonthapally API plant and cGMP approval received.
- PMDA, Japan certification received for Bonthapally and Jeedimetla API plants.
- Canada audit completed with zero observations for the Jeedimetla API plant.
- Management has signed an MoU with NIPER Mohali to establish a Centre of Excellence in Innovative and Sustainable Pharmaceutical Development.
- Construction at Genome Valley is progressing at a good pace. The company has completed its first phase in October 2023 and expects to complete its next phase by May 2024, with 2.5 billion dosage p.a. capacity. All phases are expected to be completed by December 2024, whereby Genome Valley will add 8 billion dosages p.a. capacity to the existing finished dosages capacity.
- Granules has recently launched a new greenfield packaging facility in Virginia, with which the company has enough capacity to cater to emerging new opportunities and demand in the near term.

Business overview

Granules has built one of the largest PFI and single site FD facilities in the world and has the world's largest Paracetamol API facility. Company has two research and Development (R&D) centers in Hyderabad and Virginia, alongside its existing R&D facilities in Pune and Pragathi Nagar (Hyderabad).

Company recently inaugurated integrated product Research and Development Centre at MN Park Genome Valley in Hyderabad, spanning an expansive 20,000 square feet. The center commenced its operations with a team of over 150 scientists focusing on integrated API and FD product development. Exports now contribute over 94% of overall business. Company has progressively moved from being an API to a fully integrated player with dominant finished dosage sales. Company has very strong presence in the US market, driven growth trajectory built on scale, manufacturing excellence, focused execution, and cost leadership. It is also making good inroads within Europe and contribution from the region has been on an upward trend.

During FY23, the company inaugurated the new packing facility in Manassas, Virginia, US. The facility received US FDA approval. This facility will reduce the supply chain issues, cost reduction and improvement in the working capital cycle. Granules India has seven manufacturing units, of which six are India and one in the USA.

FY22 was a challenging year for the industry with considerable headwinds around the availability and price of raw materials, solvents, catalysts, uncertainties arising out of the Ukraine-Russia conflict as well as the re-emergence of COVID-19 cases in China. The global supply chain and the logistics continue to remain under duress. The logistics costs remained at elevated levels and even pricing related challenges continued in the US market.

Active Pharmaceutical Ingredients (APIs) known as one of the most cost-effective and efficient manufacturers of APIs, the company has emerged as a leading manufacturer and supplier of Paracetamol, Metformin, Guaifenesin, and Methocarbamol. Company is working to improve API manufacturing capability to add new products. Most of the new PFI and FD products are supported by vertical integration of respective APIs. An emphasis on adopting advanced technology, backward integration to critical steps combined with the strength of a robust, resolute team, empowers to consistently meet evolving customer demands with precision and excellence. API business accounted for 30% of revenue.

Pharmaceutical Formulation Intermediates (PFI)

Company has emerged as one of India's largest PFI manufacturers with a batch processing capacity of six tons. The PFIs can be directly taken to the hoppers from the drums and it has help Granules become a preferred PFI supplier for some of the most renowned global

pharma companies. Presently, the PFI business accounts for 20% of revenue. Currently, the company has PFI facilities at Jeedimetla and Gagillapur to further process into Finished Dosages.

Finished Dosages (FD)

Over the years, Granules has sustainably grown FD capabilities and it is currently contributing over 50% of revenue. The existing portfolio of finished dosages comprises Caplets, Tablets as well as Press-fit Capsules in Bulk, Blister packs and Bottles. The manufacturing facility at Gagillapur is equipped with automated processes, robust infrastructure, and superior quality systems to efficiently produce finished dosages that are marketed in 80+ countries, including the highly regulated markets of the US and Europe. It also produces Bi-layered tablets, Rapid release tablets, and Extended release (ER) tablets. Company developed own ANDAs and dossiers to offer an added advantage to customers.

Recent Update

In Jul-2023, Granules India announced that the US FDA has approved its Abbreviated New Drug Application (ANDA), filed by Granules Pharmaceuticals, Inc. (GPI)., a wholly owned foreign subsidiary of the company, for Acetaminophen and Ibuprofen Tablets, 250 mg/125 mg (OTC). It is bioequivalent to the reference listed drug (RLD), Advil Dual Action with Acetaminophen Tablets, 250mg/125 mg (OTC), of GlaxoSmithKline Consumer Healthcare Holdings (US) LLC. This product will be launched through Granules Consumer Health (GCH) division. Acetaminophen and Ibuprofen Tablets are used for temporary relief for minor aches and pains due to: headache, toothache, backache, menstrual cramps, muscular aches, minor pain of arthritis. The Advil Dual Action with Acetaminophen Tablets (OTC) brand and store brands had combined U.S. sales of approximately US$ 70 million for the most recent twelve months based on IRI multi-outlet market data.

In Dec-2023, the company announced that the US Food & Drug Administration (US FDA) has approved its ANDA, filed by Granules Pharmaceuticals, Inc. (GPI), a wholly owned foreign subsidiary of the company, for Sildenafil for Oral Suspension, 10 mg/mL. It is bioequivalent and therapeutically equivalent to the RLDs, Revatio for Oral Suspension, 10mg/ml, of Viatris Specialty LLC. Sildenafil for Oral Suspension is indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization) in adults to improve exercise ability and delay clinical worsening. Granules has a total of 63 ANDA approvals from the US FDA (61 final approvals and 2 tentative approvals). The annual US market for Sildenafil is approximately US$ 43 million, according to MAT Sep 2023, IQVIA/IMS Health.

In Jul-2023, US FDA has issued an Establishment Inspection Report (EIR) for the Gagillapur facility of the Company located in Hyderabad, Telangana, India. This facility, that manufacturers finished dosages (FDs) and Pharmaceutical Formulation Intermediates (PFIs) was inspected by the US FDA as a part of a PAI in January 2023 which resulted in 3(three) observations during the inspection. The Company responded to these observations within the stipulated period.

In Aug-2023, Granules India Limited has received the Accreditation Certificate of Foreign Drug Manufacturer from Pharmaceuticals and Medical Devices Agency (PMDA), Japan for its Jeedimetla facility, located at Jeedimetla, Quthbullapur Mandal, Medchal Malkajgiri District, Hyderabad, Telangana. The certification has been received for accreditation categories of non-sterile Drugs, Packaging, Labelling and Storage of Drugs. Jeedimetla facility manufactures Active Pharmaceutical Ingredients (API) and Pharmaceutical Formulation Intermediates (PFIs).

In Aug-2023, Granules India Limited has received the approval from Brazilian Health Regulatory Agency (ANVISA), for compliance with the guidelines of Good Manufacturing Practices for its Bonthapally facility, located at Bonthapally Village, Gummadidala Mandal, Sangareddy District, Hyderabad, Telangana. Bonthapally facility manufactures Active Pharmaceutical Ingredients (API).

The US FDA has issued five observations to Granules Pharmaceuticals, Inc., a wholly-owned U.S.-based subsidiary of Granules India after an inspection. The Good Manufacturing Practice inspections occurred between Dec. 11 and Dec. 15.

Healthy revenue growth supported by growth across key molecules

Company reported a healthy revenue CAGR of ~21% over the past six years, supported by steady growth for some of its key molecules including paracetamol and metformin in key markets like North America, Europe and Latin America. Moreover, the growth momentum is expected to sustain over the near to medium term supported by increasing sales of its existing key molecules, increased penetration in key markets and increasing revenue contribution from new launches. The recently commissioned multiunit pellet system (MUPS) facility in Gagillapur (Telangana) and upcoming FD facility in Hyderabad are also expected to support growth momentum.

Over the years, Granules has been able to largely maintain its operating margins (18-20% range) supported by significant backward integration with in-house manufacturing of four out of five key APIs and economies of scale from its sizeable manufacturing capacities at the Gagillapur and Bonthapally (Telangana) facilities. Although the company started out as an API manufacturer, over the years it integrated its operations to manufacture FDs, which have generated ~50% of its revenues in recent years. Moreover, the commissioning of the MUPS facility and the upcoming FD facility in Hyderabad, is expected to further support its FD sales, which provide better margins. Despite some volatility due to unpredictable raw material prices and forex risks, the margins are expected to continue to remain healthy supported by its increasing backward integration (in the Kakinada project) and cost optimisation initiatives.

R&D pipeline to support growth

We expect overall business to grow at a healthy pace over the next 2-3 years, driven by the healthy abbreviated new drugs application (ANDA) pipeline of 68 products for the FD business in the US, of which 59 were approved and 12 were pending approval as on Sep-2023. The company expects to continue filing 10-12 ANDAs and launch 8-10 products per year in the US market. To support the formulation

business, the company filed six DMFs across therapies with US FDA, four certificates of suitability with the European Directorate for the Quality of Medicines and five European drug master files, which will be used for building future revenue from the API business.

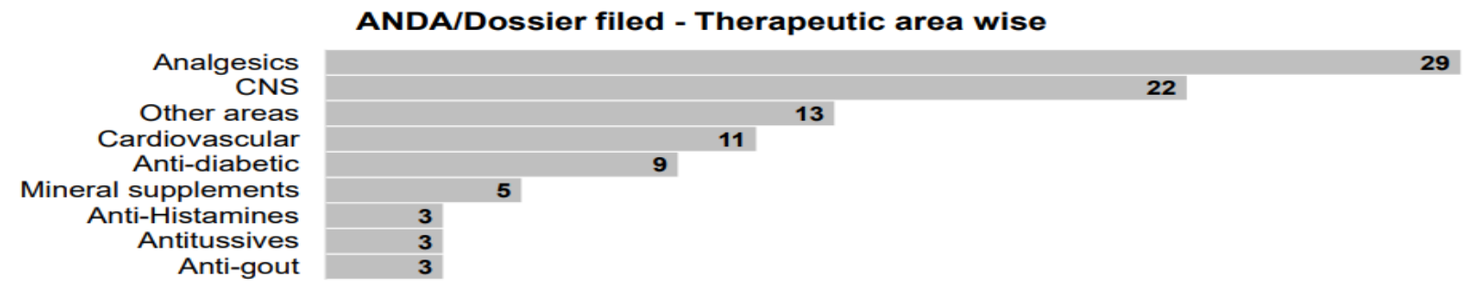
Company will continue to strengthen its market position through dedicated research and launch of new products. It intends to strengthen its product portfolio through multiple release mechanisms such as immediate release, extended release, delayed release, multiple unit pellet system, and power and suspension dosages. As part of its vertical integration strategy, Granules aims to file ANDAs for several of these APIs to forward integrate into finished dosage forms (FDFs).

Strong Business Profile

Granules' business benefits from i) the continued increase in its already large scale of operations with revenue growing at CAGR of ~18% over FY13-23 through new product launches, increased market share in existing products and increased capacities; ii) increased focus on operational efficiencies, the integrated nature of its operations and process innovation, resulting in GIL being one of the largest cost competitive suppliers of the first-line-of-defence molecules such as paracetamol, metformin, ibuprofen, guaifenesin and methocarbamol to the regulated markets; iii) increased revenue contribution from higher margin FD segment of 50% in FY23 (FY22: 52%, FY17: 37%, FY11: 22%) iv) increased proportion of sales from the regulated markets of the US and Europe (FY22: 73%, FY17: 67%, FY11: 49%); and v) no adverse regulatory action by the regulators on the company's facilities. Over the years, improvement in the product mix towards with increased revenue contribution from the FD segment, led to improvement in gross margin to 57% in FY21 from 52.6% in FY17 and 37.8% in FY11. However, gross margin reduced to 50% and 49% in FY22 and FY23. The company intends to further strengthen its business through product launches in emerging markets (Latin America and the rest of the world) that house medium-volume and medium-value products and segments with low-volume and high-value products that involve more complex R&D, niche molecules and differentiated release mechanisms from its US-based subsidiary, Granules Pharmaceuticals.

ANDA and Dossier Filing status

Filing Status	GPI IP	GIL IP						Total
	USA	USA	Europe	Canada	South Africa	UK	Others	
Approved	26	59	5	6	2	2	1	75
Tentatively Approved	-	2	-	-	-	-	-	2
To be approved	4	10	3	1	4	-	3	21
Total Products	30	72	8	7	6	2	4	98



MUPS Facility

Granules focuses on developing differentiated technologies to enable the production of complicated formulations. During the year, the company completed a new finished dosage block for manufacture of MUPS (Multi-unit pellet system) products, with an investment of Rs 240 crore. MUPS has become one of specialized manufacturing facilities. It has already received approval for a number of products and are in the process of acquiring the remaining soon. The company is one of the largest suppliers of MUPS capacity across the world on the chosen set of approved molecules, which are going to get launched in the US and Europe market. Company is evaluating opportunities to offer product, process, and related services to customers in oncology. The commercial supplies from oncology block are expected as soon as receive regulatory approvals this year.

Supply chain issues

China is opening after three years as the government has abandoned its 'zero-COVID' policy. In January-2023, China opened its borders to the world, allowing free entry, for people of China and the rest of world. It is also good news for global trade and the economy as domestic economic activities resume to pre-Covid levels. Overall, the supply situation from China is improving as manufacturers have started in full swing. The freight situation has eased off as well. Over the past few years, companies around the world have struggled with Covid-19

shutdowns, labor shortages and bottlenecks at ports, rail yards and warehouses delayed freight and drove up shipping costs. The situation seems to be easing up now as freight congestion has cleared, and ocean shipping costs have been falling towards pre-pandemic levels. However, there is still a way to go before supply-chain challenges are resolved. The solvent prices have also been softening because of gas and crude prices coming down.

R&D

The new R&D facility at Genome Valley (MN Park) for Integrated Product Development has been set up in 20,000 sq. ft. and is functioning with more than 150 scientists across both the divisions. The new facility brings API R&D and Formulation R&D teams together under one umbrella. The common analytical resources help bring efficiency in the R&D processes.

Pragathi Nagar R&D at Hyderabad, has been established as a Center of Excellence (CoE) for the development of CII APIs. In addition to CII API products, we are also focusing on the development of KSMs and Intermediates for select APIs. To further strengthen presence in Controlled Substances, the company will continue to leverage research and development capabilities of Pragathi Nagar, in conjunction with the FD R&D of subsidiary, Granules Pharma Inc. (GPI).

The Bio Lab brings capabilities in the areas of fermentation and biotransformation along with lab and pilot scale manufacturing platform for the Enzyme led projects. R&D initiatives would help broaden capabilities, leading to increased focus on quality of portfolio and higher number of regulatory filings going forward.

US generics market

The US generic pharma industry has been grappling with pricing pressure, supply chain issues, and cost inflation, and that's why severely impacting margin of the players. It is attributed to several factors such as customer consolidation, intensified competition, and the US government's measures to reduce drug prices for customers. Company faced high single digit price erosion for FY23. The resultant pricing pressure would lead to the consolidation of the industry towards the stronger players who have better control over the supply chain and are capable of backward integration through innovative manufacturing technology.

Additionally, the COVID-19 pandemic posed significant Raw material pricing challenges for pharmaceutical companies, with key raw material shortages due to China's shutdown. The recent geopolitical instability caused by the Russia-Ukraine war has also led to energy and logistical cost increases. However, with the situation gradually improving, these challenges are expected to diminish, and the industry can potentially regain its footing.

European (EU) Region

Spending in Europe is expected to increase by US$ 59 billion over the period 2023-2027, with a focus on generics and biosimilars, and escalating pressures on the value and negotiated prices of novel medicines.

Generics, including biosimilars, are expected to add US$ 12 billion in growth over the next five years (2023-27), about the same as in the past five years despite a larger impact of losses of exclusivity as volume gains will be offset by price deflation.

The impact of losses of exclusivity in the five largest European markets (Germany, France, Italy, Spain and the UK) are expected to be more than triple over the next five years, and more than half of the impact is expected to be biologics. Small molecule is expected to double in terms of impact on brands in the next five years even as they have been a smaller share of overall impact.

Japan

Japan's medicine spending growth is projected at -2 to 1% over the period (2023-27) as strong brand growth is offset by a shift in annual price cuts and ongoing moves to generics. Generic's share of spending in Japan is also expected to rise, supported by policies that have been largely effective over this entire 15-year period, encouraging doctors to substitute available generics with a combination of incentives and penalties.

Over the Counter (OTC) Drugs Market

OTC or over-the-counter drugs are pharmaceutical products that are perceived to be safe to buy without prescription and are used to treat common symptoms for cold, body pain, allergy, flu, heartburn, acne, and other basic health problems. As per Global Market Insights Report of 2020, the OTC drugs market size was valued at US$ 152 billion in 2020 and is expected to grow at a CAGR of over 5.1% to reach US$ 209 billion in 2027. Emergence of COVID-19 has affected millions of people across the globe, affecting several industrial sectors. The outbreak has considerably influenced the sales of OTC drugs with increased focus on personal health during the pandemic. This has significantly augmented the intake of cold and flu products besides vitamins. However, in some regions, OTC drug sales were restricted to counteract stockpiling and maintain supply. Increasing availability and manufacturing of OTC drugs for a broad range of common disease conditions will significantly drive the over-the-counter drugs market revenue in the impending years. Repetitive occurrence of common flu and cold impels the demand for therapeutics. Awareness on and demand for vitamin supplements and weight loss products will majorly contribute to the industry value during the forecast period i.e. from 2020 to 2027. Cost-benefits, positive results and broader accessibility are projected to highly fuel demand for over-the-counter drugs.

Key Concerns

- Vulnerability in business due to currency movements, regulatory changes and geopolitical events across the countries. Company derives about 90% of sales from US, Europe, LatAm and RoW markets. IT has also borrowed debt in foreign currency.
- Elevated price erosion in the US generic business could hurt US revenue though pricing pressure has moderated and is currently in high single digit.
- Any disruption in sourcing KSMs as Granules depends on China for some of its products and any increase in prices of raw materials could weigh on net profit earnings estimates.
- Any escalation of regulatory issues at its key facility or delay in its resolution could weigh on earnings.
- High product concentration risk in mature molecules, although mitigated to some extent by healthy market share in these molecules. The top five molecules are first line of defence mature generic molecules. The company is exposed to product concentration risk as these molecules have continued to account for 80-85% of its revenues in recent years.
- A significant share of revenue is generated by North America (~52-57%) and Europe (18-23%), which have witnessed continued pricing pressure over the recent past, which is likely to sustain. However, the risk is mitigated to a certain extent by GIL's market leadership for some of these key molecules in its key markets. Moreover, the company has focused on enhancing its footprint in Europe and Latin America. With increased focus on R&D, new launches are expected to improve, going forward. However, a few key molecules would continue to contribute meaningfully to revenue.
- Granules' profitability continues to remain vulnerable to volatility in raw material prices, though its backward integrated operations provide some comfort. The capex plan in Kakinada (Andhra Pradesh) for manufacturing KSMs of its key products like paracetamol and metformin, which is expected to further support its profitability against volatility in raw material prices over the medium to long-term.
- Not unlike its peers, Granules India continues to remain exposed to regulatory risks and litigations including scrutiny by agencies like US FDA and EU GMP. Considering the US contributed ~50% to its revenue in FY23, scrutiny by the US FDA continues to remain key for its overall operations. Granules' Gagilapur (Telangana) facility, which had received a Form 483 with three observations by the US FDA post inspection in January 2023, has subsequently received an establishment inspection report. Moreover, its two other facilities at Jeedimetla (Telangana) and Visakhapatnam (Andhra Pradesh) also completed US FDA inspections in Jun-2023 with zero Form 483 observations. It got 5 observations in the US FDA inspection of its US subsidiary in Dec 2023.
- Granules is in the midst of a large capex. Apart from execution risks it also faces the risk of underutilization of capacity once these projects get commissioned.

Company Background

Granules India Ltd. was incorporated as a private limited company in 1991 and was later converted into a public limited company in 1993. It started out as a merchant exporter of bulk drugs like paracetamol, Guaifenesin and Chloro Pheniramine Maleate. Granules India manufactures APIs, pharmaceutical formulation intermediates (PFIs) and FDs, which are marketed to more than 300 customers across more

than 50 countries, primarily in North America, Europe, Asia and Latin America. Company has seven manufacturing plants across Hyderabad, Visakhapatnam and Virginia (USA), and two R&D centres in Hyderabad and Virginia, with an installed manufacturing capacity of 39,360 TPA of API, 24,640 TPA of PFI and 23.3 billion dosages of FDs.

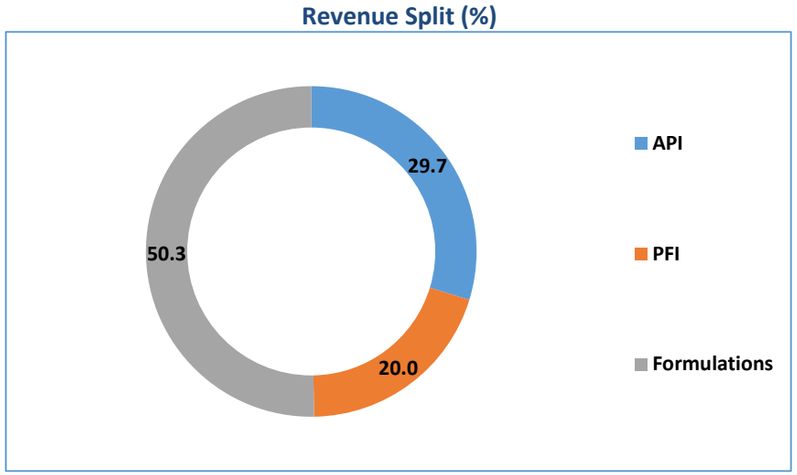
The products are being distributed to over 300+ customers in regulated and semi-regulated markets with a global presence extending to over 80+ countries with offices across India, US, and UK. Company has 7 manufacturing facilities out of which 6 are in India and 1 in the USA and 1 packaging facility in the USA and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC etc.

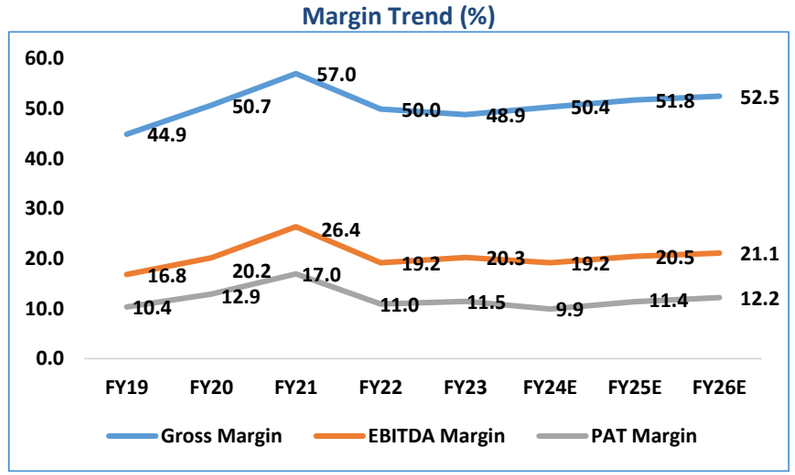
Granules India Limited (GIL) is a leading, vertically integrated pharmaceutical Company dedicated to manufacturing Active Pharmaceutical Ingredients (API), Pharmaceutical Formulation Intermediates (PFI) and Finished Dosages (FD) products. Company has presence across the United States of America, Canada, Latin America, Europe, Asia, and India. It has two state-of-the-art R&D centres are in Hyderabad and Virginia. Exports contribute to over 90% of revenue. Company has progressively moved from being an API to a fully integrated player with dominant finished dosage sales. It is making good inroads within Europe and contribution from the region has been on an upward trend. During the year, the company completed new finished dosage block for the manufacturing of MUPS (multi-unit pellet system) products in existing manufacturing plant.

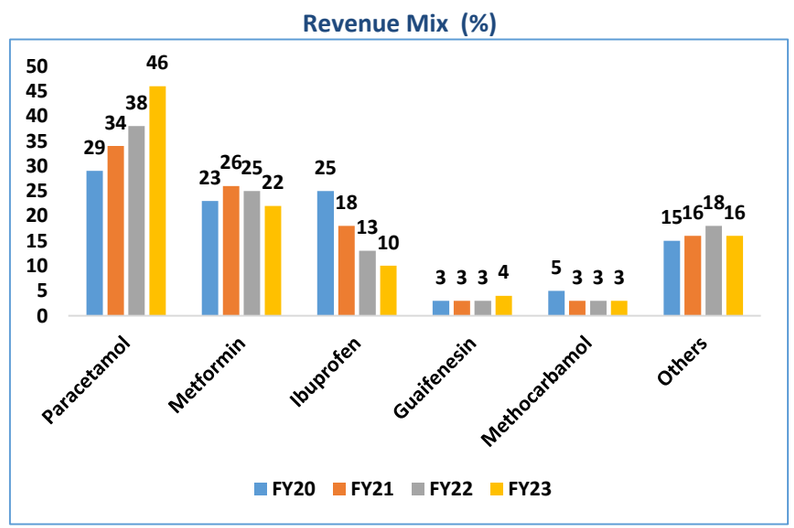
Manufacturing Facilities

	Manufacturing Units	Capacity	Regulatory Approvals
API	▸ Bonthapally, Telangana	▸ 34,560 TPA	▸ U.S. FDA, EDQM, WHO, COFEPRIS,INFARMED
	▸ Jeedimetla, Telangana	▸ 4,800 TPA	▸ U.S. FDA, EDQM, COFEPRIS, WHO, CDCSO
	▸ Vizag (Unit IV), Andhra Pradesh	▸ 380 KL	▸ U.S. FDA, KFDA, EU GMP, WHO GMP, EDQM
	▸ Vizag (Unit V), Andhra Pradesh	▸ 15 KL	▸ EU GMP
	▸ Bonthapally II (API Intermediate, Telangana)	▸ 61.5 KL	
PFI	▸ Gagillapur, Hyderabad	▸ 23,200 TPA	▸ US FDA, COFEPRIS, TGA, MCC, INFARMED
	▸ Jeedimetla, Telangana	▸ 1,440 TPA	▸ WHO GMP, COFEPRIS, INFARMED
FD	▸ Gagillapur, Hyderabad	▸ 26.8 Bn	▸ US FDA, MCC, COFEPRIS, TGA, INFARMED
	▸ Virginia, USA	▸ 1.5 Bn	▸ US FDA, DEA
	▸ Vizag (Unit V), Andhra Pradesh	▸ 1.1 Bn	▸ EU GMP
Packaging	▸ Virginia, USA	▸ 2 OTC lines and 1 Rx line	▸ US FDA

Granules India Ltd.







(Source: Company, HDFC sec)

Granules India Ltd.

Financials (Consolidated)

Income Statement

(Rs cr)	FY21	FY22	FY23	FY24E	FY25E	FY26E
Total Revenue	3238	3765	4512	4792	5381	5973
Growth (%)	24.6	16.3	19.8	6.2	12.3	11.0
Operating Expenses	2382	3043	3598	3872	4278	4712
EBITDA	**855**	**722**	**914**	**920**	**1103**	**1261**
Growth (%)	62.8	-15.5	26.5	0.7	20.0	14.3
EBITDA Margin (%)	26.4	19.2	20.3	19.2	20.5	21.1
Depreciation	152	159	184	208	231	249
EBIT	704	564	730	712	872	1012
Other Income	27	18	14	16	19	23
Interest expenses	26	23	56	87	61	48
PBT	704	558	687	641	830	987
Tax	155	145	171	165	215	256
RPAT	**550**	**413**	**517**	**476**	**615**	**731**
Growth (%)	63.8	-24.9	25.2	-7.9	29.2	18.9
EPS	22.2	16.6	21.4	19.6	25.4	30.2

Balance Sheet

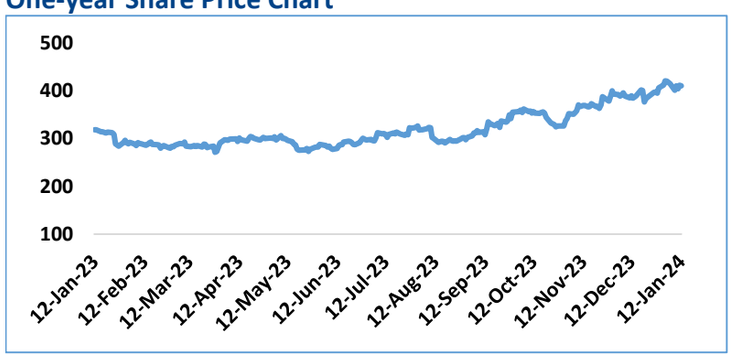
As at March (Rs cr)	FY21	FY22	FY23	FY24E	FY25E	FY26E
SOURCE OF FUNDS						
Share Capital	24.8	24.8	24.2	24.2	24.2	24.2
Reserves	2149	2562	2811	3272	3865	4570
Shareholders' Funds	**2173**	**2587**	**2835**	**3297**	**3889**	**4594**
Long Term Debt	334	234	149	158	170	175
Net Deferred Taxes	-5	1	-5	-5	-5	-5
Long Term Provisions & Others	32	37	100	108	115	123
Total Source of Funds	**2534**	**2858**	**3079**	**3558**	**4169**	**4887**
APPLICATION OF FUNDS						
Net Block (incl. CWIP)	1256	1596	1858	2080	2249	2350
Intangible Assets	315	302	291	291	291	291
Non-current Investments	19	20	21	28	35	44
Long Term Loans & Advances	120	78	148	141	131	122
Total Non Current Assets	**1710**	**1995**	**2318**	**2540**	**2706**	**2806**
Inventories	782	979	1149	1037	1143	1276
Trade Receivables	765	925	949	1053	1176	1306
Short term Loans & Advances	10	8	1	2	3	7
Cash & Equivalents	271	409	313	504	713	1013
Other Current Assets	169	184	163	178	201	243
Total Current Assets	**1997**	**2506**	**2574**	**2773**	**3236**	**3845**
Short-Term Borrowings	505	859	910	883	812	698
Trade Payables	541	639	782	732	794	869
Other Current Liab & Provisions	115	122	107	120	136	153
Short-Term Provisions	13	23	15	20	30	45
Total Current Liabilities	**1174**	**1643**	**1814**	**1755**	**1772**	**1765**
Net Current Assets	824	863	761	1018	1463	2081
Total Application of Funds	**2534**	**2858**	**3079**	**3558**	**4169**	**4887**

Granules India Ltd.

Cash Flow Statement

(Rs cr)	FY21	FY22	FY23	FY24E	FY25E	FY26E
Reported PBT	704	558	687	641	830	987
Non-operating & EO items	-27	-18	-14	-16	-19	-23
Interest Expenses	26	23	56	87	61	48
Depreciation	152	159	184	208	231	249
Working Capital Change	-231	-245	1	-67	-236	-317
Tax Paid	-191	-145	-176	-165	-215	-256
OPERATING CASH FLOW (a)	**433**	**332**	**739**	**688**	**653**	**689**
Capex	-271	-398	-411	-430	-400	-350
Free Cash Flow	162	-66	328	258	253	339
Investments	-33	0	205	0	3	1
Non-operating income	27	18	14	16	19	23
INVESTING CASH FLOW (b)	**-277**	**-380**	**-192**	**-414**	**-379**	**-327**
Debt Issuance / (Repaid)	-71	251	-55	18	19	13
Interest Expenses	-26	-23	-56	-87	-61	-48
FCFE	64	161	217	189	210	304
Share Capital	0	0	-1	0	0	0
Dividend/Buyback	-202	-37	-329	-14	-23	-26
FINANCING CASH FLOW (c)	**-299**	**190**	**-441**	**-83**	**-65**	**-62**
NET CASH FLOW (a+b+c)	**-144**	**142**	**107**	**191**	**209**	**301**

One-year Share Price Chart



Key Ratios

	FY21	FY22	FY23	FY24E	FY25E	FY26E
Profitability (%)						
Gross Margin	57.0	50.0	48.9	50.4	51.8	52.5
EBITDA Margin	26.4	19.2	20.3	19.2	20.5	21.1
EBIT Margin	21.7	15.0	16.2	14.9	16.2	16.9
APAT Margin	17.0	11.0	11.5	9.9	11.4	12.2
RoE	27.4	17.3	19.1	15.5	17.1	17.2
RoCE	27.7	19.6	23.6	19.9	20.9	20.7
Solvency Ratio (x)						
Net Debt/EBITDA	0.7	0.9	0.8	0.6	0.2	-0.1
D/E	0.4	0.4	0.4	0.3	0.3	0.2
Net D/E	0.3	0.3	0.3	0.2	0.1	0.0
PER SHARE DATA (Rs)						
EPS	22.2	16.6	21.4	19.6	25.4	30.2
CEPS	28.3	23.0	29.0	28.2	34.9	40.4
BV	88	104	117	136	160	190
Dividend	0.6	0.4	0.4	0.5	0.9	1.0
Turnover Ratios (days)						
Debtor days	86	90	77	80	80	80
Inventory days	69	85	86	79	78	78
Creditors days	109	96	98	87	86	86
VALUATION (x)						
P/E	19.3	25.8	20.1	21.8	16.9	14.2
P/BV	4.9	4.1	3.7	3.2	2.7	2.3
EV/EBITDA	13.3	15.8	12.5	12.4	10.3	9.0
EV / Revenues	3.5	3.0	2.5	2.4	2.1	1.9
Dividend Yield (%)	0.1	0.1	0.1	0.1	0.2	0.2
Dividend Payout	2.7	2.4	1.9	2.5	3.4	3.3

(Source: Company, HDFC sec)

KUSHAL MAHENDRA RUGHANI

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HDFC Sec Research Rating description

Green Rating stocks

This rating is given to stocks that represent large and established business having track record of decades and good reputation in the industry. They are industry leaders or have significant market share. They have multiple streams of cash flows and/or strong balance sheet to withstand downturn in economic cycle. These stocks offer moderate returns and at the same time are unlikely to suffer severe drawdown in their stock prices. These stocks can be kept as a part of long term portfolio holding, if so desired. This stocks offer low risk and lower reward and are suitable for beginners. They offer stability to the portfolio.

Yellow Rating stocks

This rating is given to stocks that have strong balance sheet and are from relatively stable industries which are likely to remain relevant for long time and unlikely to be affected much by economic or technological disruptions. These stocks have emerged stronger over time but are yet to reach the level of green rating stocks. They offer medium risk, medium return opportunities. Some of these have the potential to attain green rating over time.

Red Rating stocks

This rating is given to emerging companies which are riskier than their established peers. Their share price tends to be volatile though they offer high growth potential. They are susceptible to severe downturn in their industry or in overall economy. Management of these companies need to prove their mettle in handling cyclicality of their business. If they are successful in navigating challenges, the market rewards their shareholders with handsome gains; otherwise their stock prices can take a severe beating. Overall these stocks offer high risk high return opportunities.