

# Re-Initiating Coverage Alkem Laboratories Ltd.

25 November-2020





Industry	LTP	Recommendation	Base Case Fair Value	Bull Case Fair Value	Time Horizon
Pharmaceuticals	Rs 2774.55	Buy at LTP and add on dips to Rs 2534-2542 band	Rs 3020	Rs 3223	2 quarters
		- Our Take		\	

HDFC Scrip Code	ALKLABEQNR
BSE Code	539523
NSE Code	ALKEM
Bloomberg Code	ALKEM: IN
CMP Nov 24, 2020	2774.55
Equity Capital (Rs cr)	23.9
Face Value (Rs)	2
Equity Share O/S (cr)	11.95
Market Cap (Rs cr)	33174
Book Value (Rs)	515.3
Avg. 52 Wk Volumes	134348
52 Week High	3089.55
52 Week Low	1950

Share holding Pattern %	(Sep, 2020)
Promoters	62.4
Institutions	16.8
Non Institutions	20.8
Total	100.0

#### **Fundamental Research Analyst**

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Alkem Labs has been the No. 1 Anti-infectives (~10% market share) player in India for over 15 years. It is the No. 3 gastrointestinal and vitamins (VMN) company in India. It is ranked No. 5 in the Indian Pharma Market (IPM) as on Mar-2020. Company has 8 brands with annual sales of more than Rs 100cr each, 4 brands features amongst the top 50 pharmaceutical brands and 7 brands features in top-100 brands in India while 14 brands feature amongst the top 300 pharmaceutical brands in India. Alkem continues to remain the industry leader for Anti-Infectives in India and expects to grow by 1.5x industry growth in the overall acute segment. Domestic formulations business contributed ~67% of total revenues and has consistently outperformed industry over the years. We believe FY21 is likely to be a relatively subdued year for Alkem due to its high dependence on acute portfolio (the most impacted by lockdown). However, trade generics has witnessed strong traction and also vitamins portfolio has seen strong demand.

Off late, Alkem has increased its focus on introducing new products to meet identified therapy gaps across its established therapeutic segments. Company derives 60-65% of its domestic revenues from acute segment. Alkem's overall share in chronic segment is at 1.6%. It has gained ~70bps over the last 7 years. It has improved its ranks across key therapeutic segments - cardiac, anti-diabetes and CNS by launching new products and gaining market share in most of its top 10 molecules in each of these therapies. The differentiated product offerings in these new therapy areas will enable the company to grow and diversify its portfolio. While a strong and long anti-infective season helped Alkem in supernormal FY20, Alkem's leadership position in its legacy brands and therapies along with improved standing in chronic space would ensure above-average growth. It has sufficient capacity for the next 2-3 years. US business has seen 22% revenues CAGR led by steady base business and new launches over FY17-20. We estimate 18% revenues CAGR in US sales over FY20-23E. R&D spends has been in the range of 5-6% of revenues and are likely to remain in the same levels in the next 2-3 years. Long-term API procurement contracts will ensure stable gross margins. We like Alkem's volume driven growth in India aided by strong brands and deep penetration, which is reflected in its domestic revenue growth that is in-line/higher than broader market despite the high acute exposure.

#### **View & Valuation**

Alkem's chronic business continued to grow significantly ahead of the market growth rate, leading to improvement in its market share and ranking in therapy segments of CNS, anti-diabetic, cardiology and dermatology. International Business mainly led by US, delivered a robust performance on the back of new product launches and market share gains in the company's existing products. Company looks to



outperform in the chronic segment on the back of 1) new product launches including in-licensed products 2) effective sales and marketing strategies 3) improved sales force productivity and 4) building strong brands. We believe there is good headroom for growth in the US market. In H1FY21, the company registered 28% yoy growth in the US business led by new launches and market share gain. Alkem has cumulatively filed 147 ANDAs with the US FDA out of these 56 are pending for approval, it has cGMP compliant manufacturing facilities and own front end to distribute and market its products. We expect 10.4% CAGR growth in revenues on led by strong 18% growth in US business and 7% CAGR in India business over FY20-23E. Higher profit contribution from chronic portfolio, improving MR productivity and rising scale in US generics will drive margin expansion of ~450bps over FY20-23E. Healthy revenues and steady margin of around 21-23% would lead to strong 18% CAGR in PAT over the same period. Return ratios would improve with margin expansion led by healthy growth in India and strong growth in US business.

Alkem has strong market positions in anti-infective, gastrointestinal and pain segments and is a leader in acute therapy segments. In recent years, it has entered into chronic segments such as cardiology, anti-diabetics & dermatology. Its domestic business should benefit from focus on MR productivity improvement. Alkem has built a decent platform for growth in the US with its diversified manufacturing base (6 FDA approved facilities, including 2 in the US), pipeline of 74 ANDAs (~75 products approved) and front-end presence. Its US business targets 12-15 filings and 10+ launches every year. Alkem's prudent capital allocation framework and refraining from investments in high risk areas resulting in better return ratios and that appeals to a lot of investors.

Earlier, on May 28, 2020 we had recommended buy on Alkem Labs with price target of Rs 2703. The stock achieved our target as the company had registered stellar numbers for Q1FY21. The stock had touched high of Rs 3089 in Aug-2020.

We remain positive on the long-term outlook considering the company's strong brand presence in the domestic market with sustainable growth and scale up of US generic business. Strong brand equity in the domestic market, robust balance sheet and return ratios support our positive view on the stock. We feel investors can buy the stock at LTP and add on decline to Rs.2534-2542 band (18.5x FY22E EPS) for base case target of Rs 3020 (22.0x FY22E EPS) and bull case target price of Rs 3223 (23.5x FY22E EPS) over the next two quarters.



#### **Financial Summary (Consolidated)**

Particulars (Rs cr)	Q2 FY21	Q2 FY20	YoY (%)	Q1 FY21	QoQ (%)	FY19	FY20	FY21E	FY22E	FY23E
Total Revenues	2363	2264	4.4	2004	17.9	7,357	8,344	9,053	10,094	11,235
EBITDA	601	453	32.6	533	12.7	1115	1474	2039	2172	2491
Depreciation	70	56	24.5	67	5.1	193	253	277	298	327
Other Income	36	31	13.1	44	-18.4	88	104	139	154	169
Interest Cost	18	18	1.1	17	5.9	55	65	73	67	63
Tax	66	29	125.9	70	-4.9	181	110	238	292	386
APAT	472	371	27.2	422	11.8	761	1127	1563	1639	1847
EPS (Rs)						63.6	94.3	130.7	137.1	154.5
RoE (%)						14.8	19.4	23.1	20.4	19.7
P/E (x)						43.5	29.4	21.2	20.2	17.9
EV/EBITDA (x)						29.6	22.4	16.2	15.2	13.2

(Source: Company, HDFC sec)

#### Q2 FY21 result highlights

Alkem reported strong earnings in what was expected to be a muted quarter given the impact on acute prescriptions due to COVID and the strong seasonality in the last year. It was led by strong growth in chronic segment while US business registered ~19% yoy growth led by new launches and market share gains for the quarter. In Q2 the key driver of Alkem's domestic business was trade generics, which grew 36% (~25% of India sales) while its branded formulations declined 8%. With a rise in patient visits in H2FY21, management expects its branded business to grow in double digit while traction in trade generics may be modest. EBITDA margin rose 540bps yoy to 25.4% on better product mix (gross margins expanded 40bps) and lower promotional cost. PAT for the quarter grew 27% yoy led by strong margin expansion. Normalization of other expenses could be more gradual and that is likely to benefit margins in the near term particularly as revenues recover. Management indicated that around 30% of spend on promotional material, conferences, etc. are unlikely to normalize in the next few quarters with the increased use of digital. Company filed 1 ANDA and received 4 approvals in Q2 FY21. It has launched 6-7 products in H1FY21 and maintains its stance of launching a total of 10-12 ANDAs in FY21. Alkem ranks 15th in the domestic chronic market. Cardiac and Diabetic portfolio is growing at healthy double digits # In the US market, the company launched 6-7 products in H1FY21. Management targets 10-12 in FY21. Management mentions that over next 2-3 years, EBITDA margins should be at ~20-23%.



#### **Domestic formulations business outlook**

Alkem registered growth of 17% yoy in FY20, which was more than 1.5x the IPM growth of 10.8%. As a result, the Company gained one rank during the year and now features amongst the top 5 pharmaceutical companies in India in terms of market share. This outperformance was broad-based as the company grew faster than the market growth rate in most of the major therapy areas of its presence. In its established therapy segments of anti-infectives, gastrointestinal and VMN (vitamins / minerals / nutrients), the company grew ahead of the market growth, thereby consolidating its position amongst the top companies in these therapeutic segments. Alkem is an established player with large brands and over four decades of presence in these areas. The company continues to rank as the no. 1 antiinfectives player in India for over 15 years and also features amongst the top 5 pharma companies in the therapy areas of gastro intestinal, pain & analgesic and VMN. This performance has been driven by Company's market leading brands, large field force, robust supply chain and distribution network, comprehensive product portfolio, introduction of new products. Company's top 10 brands feature amongst the top 2 selling brands in their respective molecule category and have been growing at a steady pace. Company launched 37 new products including line extensions during the last year. The company introduced two novel molecules in India - Arbekacin in Anti-Infective segment and Evogliptin in Anti-Diabetic segment. Both of these are in-license products and are exclusively marketed by Alkem, as per the terms of the agreement. In the gastro-intestinal segment, Alkem offers products to treat disorders like hyperacidity, gastric ulcers, nausea, vomiting, diarrhoea, GERD (Gastroesophageal Reflux Disease) and worm infestation. Its leading antibiotic brand, Clavam, is the second largest selling brand in the molecule category as on Mar-2020. Alkem has other leading brands, Pan, Pan-D, Xone, Taxim and Taxim-O, among a total of 7 brands that feature in the top 100 revenue generating brands in India. Company derived ~61% of its domestic revenues from acute therapeutic area while sub-chronic and chronic contributed to 24% and 15% respectively in FY20.

In the chronic segments of neurology/CNS, dermatology, anti-diabetes and cardiology, the company is an emerging player with growing product portfolio and rising market share. Alkem has several new products lined up in the vitamins, minerals and nutrients (VMN) segment along with the nutraceuticals in the areas of pregnancy, bone-health, gastrointestinal, among others. Alkem is consolidating its existing offerings in the pain/analgesic segment through brand building initiatives.

The chronic segment is also poised to be an important driver of industry growth with cardiac (CVS) and Anti-Diabetic being amongst the fastest growing therapy areas in the country. Alkem has set up specialised divisions for CVS, Anti-Diabetic, urology, CNS and dermatology to focus on the right brands within each of these segments.



#### US Business set to grow at ~18% CAGR over FY20-23E

Despite being a late entrant, Alkem Labs has demonstrated good execution in the US (fair market share in the products launched). US revenues (US\$ 309mn in FY20) grew at 23% CAGR over the last 5 years. Alkem entered into US in FY11 and adopted inorganic route with acquistions, which enabled them to establish presence in US and also diversify its manufacturing capabilities in dosage form like semi-solid, liquid and nasal formulations. It has managed to navigate pricing pressure on generics and has managed to break even couple of years back. US business contributed to around 26.4% to its total revenues. During FY20, US business registered 16% yoy growth at Rs 2200cr. In dollar terms, revenues from the US market crossed US\$ 300mn during the financial year. The strong growth during the last year was mainly on account of market share gains in the existing products as well as contributions from the new product launches. Favourable exchange rate movement also helped to report strong year-on-year growth during the year. We expect new product launches (10-12 per year) to offset base business erosion (mid-single digit) and drive 17.5% revenue CAGR over the next three years. Key formulation plants - Baddi, Daman, St. Louis and API plants - Ankleshwar, Mandva, California have received EIRs and that augurs well for the company.

During the last year, the company filed 18 ANDAs with the US FDA and received 22 approvals (including 6 tentative approval). Company has cumulatively filed 147 ANDAs including 2 new drug applications (NDA) with the US FDA. Of these, it has received approvals for 91 ANDAs (including 13 tentative approvals) and 2 NDA. The approved NDAs include brand Marinol (Dronabinol) which the company acquired from AbbVie Inc, USA in Dec-2019. In H1 FY21, the company filed 5 ANDAs with the US FDA and received 6 approvals (including 2 tentative approval).

#### **US FDA inspections update**

May 2019 - US FDA inspected Company's formulation manufacturing facility at Baddi. Company received Form 483 containing four observations. Subsequently, the company received an EIR in Jul-2019, thereby closing the inspection successfully.

August 2019 - US FDA carried out inspections at Company's formulation manufacturing facilities at Baddi and St. Louis (Fenton Park). At the end of the inspection, no Form 483 was issued for Baddi facility, however, St. Louis facility received Form 483 containing four observations. Subsequently, the company received an EIR in Sep-2019, thereby closing the inspection at St. Louis facility successfully.

August 2019 - Company's formulation facility at Daman was inspected by US FDA. Company received Form 483 containing two observations. Subsequently, the Company received an EIR in Oct-2019, thereby closing inspection successfully.



October 2019 - US FDA inspected Company's bioequivalence facility located at Taloja. At the end of the inspection, no Form 483 was issued.

Jan-Feb 2020 - Inspection was conducted by US FDA at Company's formulation manufacturing facility at St. Louis. At the end of the inspection, company received Form 483 containing three observations. Subsequently, the company received an EIR in May-2020, thereby closing inspection successfully.

February 2020 - US FDA inspected Company's formulation facility at Baddi. At the end of the inspection, the Company received Form 483 containing two observations. Subsequently, the Company received an EIR in Mar-2020, thereby closing the inspection successfully.

#### Other International Markets

Company has wide presence in more than 40 international markets with its key markets being Australia, Philippines, Chile and Kazakhstan. Its products are sold either directly through its own subsidiaries or indirectly through active engagement with other companies in Australia, Chile, Philippines, Kazakhstan, Europe, Middle East and East Africa. During FY20, the company's total revenues from Other International Markets business grew by 8.7% yoy to Rs 538cr. Company said that it would focus more on the US market as it has huge potential to grow and therefore continues to rationalise some of the low-margin areas in the rest of the world (RoW).

Growth was driven by new product launches (including in-licensed products) and improving market share in existing products. The key markets of Australia, Chile, Philippines and Kazakhstan registered healthy growth during the year which was complimented by steady growth in Middle East and African markets. The company has filed more than 1,100 dossiers across international markets with more than 750 approvals. To augment the growth in these markets, the Company is focusing on introducing new products, growing its share in existing products and through strategic acquisitions/partnership agreements for product in-licensing and out-licensing. RoW business contributed to 6.5% of revenues. We expect steady 9% CAGR in revenues over FY20-23E. Volatile currency movements remain a key challenge for the business.



#### **R&D** spends & Biosimilar segment

Alkem has been consistently investing a substantial part of its revenue into R&D over the years. Backed by a team of over 500 scientists working in six R&D centres across US and India, the company has a robust pipeline of products to fuel future growth. During FY20, the company spent Rs 473cr or 5.7% of its revenues on R&D.

Company has also made substantial investments in the biosimilars segment through its subsidiary Enzene Biosciences - a biotech focused on R&D situated at Pune. Over the medium to long-term, Enzene aims to launch biosimilar products which are in preclinical and clinical development stage in India and core international markets. Company said that it would be launching first biosimilar product in India from its R&D and manufacturing facility in FY21.

Alkem has invested ~Rs 500cr in biosimilar/biotech space through Enzene Bioscience (99.9% stake) over the last five years. It has built capabilities in manufacturing monoclonal antibody (mAbs). Enzene's pipeline includes around 8 biosimilars. It plans to launch 3 products (two peptides, one mAb) in India by end of FY21. Company said that annual operating spends on biosimilars is at around Rs 80cr. Alkem plans to enter RoW markets in the medium term via out-licensing deal. For the regulated markets like US, the company does not have visibility until FY25.

#### **Key Risks/Concerns**

- Adverse pricing regulations by the National Pharmaceutical Pricing Authority (NPPA) in India on prices of key products could reduce revenue and squeeze margins.
- Company has strong presence in the acute segment which is seasonal in nature.
- Elevated price erosion in the US generic business could hurt the performance though pricing pressure has moderated and is currently in low single digit. Also Incremental competition in existing key products in US business can impact growth.
- Delay in approvals/launches or surprise competition in niche products may lead to lower growth in the US business.
- Any adverse US FDA action upon inspection of its US dedicated facilities would hinder revenues growth.
- Delay in launching biosimilar products or Inability to monetize the investments made in this segment can impact earnings.
- Adverse currency movement may impact its profitability.
- Disruption in the trade generics business due to regulatory action could be a key risk to the stock since this accounts for 15% of overall domestic sales. Further, any slowdown in IPM growth and delay in new launches can affect earnings.



#### **Company Background**

Alkem Laboratories is a leading Indian generic pharmaceutical company with global operations. Founded in 1973, Alkem is engaged in the development, manufacture and sale of pharmaceutical and nutraceutical products which are marketed in India and overseas. The company has consistently ranked amongst the top ten pharmaceutical companies in India, backed by an extensive portfolio of over 800 brands, wide sales and distribution network pan-India, and an experienced management team. Over the years, the Company has established its position as one of the leading companies in India in the acute therapy areas of Anti-infective, Gastro-intestinal, Pain management and Vitamins/Minerals/Nutrients (VMN) products. In addition, it has been constantly enhancing its presence in the chronic therapy areas of Neuro/CNS, Cardiac, Anti-diabetes and Dermatology. The Company has a strong foothold in India and a growing presence in over 40 international markets, with the US being the key market. It has infrastructure comprising of 21 manufacturing facilities and six R&D Centres across India and the US. The manufacturing facilities have been approved by the US FDA, World Health Organisation (WHO), MHRA (UK), TGA (Australia), ANVISA (Brazil) and MCC (South Africa).

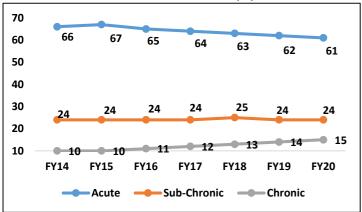
#### **Peer Comparison**

		Мсар	Revenues	Operating	PAT*	RoE*	RoCE*	P/E*	EV/EBITDA	P/B*
Company	СМР	(Rs cr)	* (Rs cr)	Profit* (Rs cr)	(Rs cr)	(%)	(%)	(x)	* (x)	(x)
Torrent Pharma	2622	44374	9211	2683	1426	21.8	18.0	30.5	16.2	6.7
Alkem Labs	2775	33174	10094	2172	1639	20.4	18.1	20.2	15.2	3.8
Cadila Healthcare	429	43929	16613	3485	2033	16.2	13.1	21.5	13.8	3.3
Lupin	895	40577	18331	3577	1917	12.8	10.0	21.5	11.7	2.6

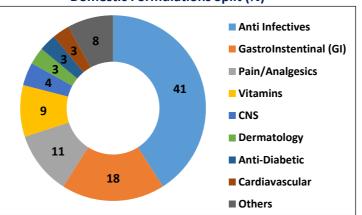
Source: Company, HDFC sec Research \*FY22E Consolidated



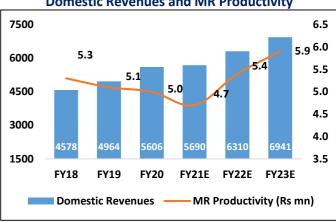




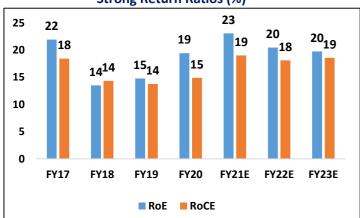
#### **Domestic Formulations Split (%)**



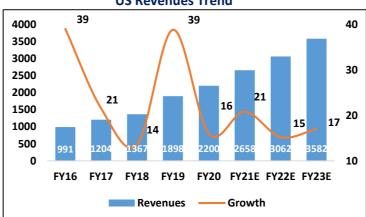
#### **Domestic Revenues and MR Productivity**



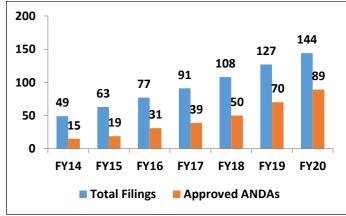
Strong Return Ratios (%)







#### **ANDA Filings and Approvals (#)**



Source: Company, HDFC sec Research



#### **Income Statement**

(Rs Cr)	FY19	FY20	FY21E	FY22E	FY23E
Total Revenues	7357	8344	9053	10094	11235
Growth (%)	14.9	13.4	8.5	11.5	11.3
Operating Expenses	6242	6870	7014	7922	8744
EBITDA	1115	1474	2039	2172	2491
Growth (%)	10.5	32.2	38.4	6.5	14.7
EBITDA Margin (%)	15.2	17.7	22.5	21.5	22.2
Depreciation	193	253	277	298	327
EBIT	922	1221	1762	1875	2164
Other Income	88	104	139	154	169
Interest expenses	55	65	73	67	63
PBT	955	1258	1831	1960	2268
Tax	181	110	238	292	386
PAT	761	1127	1563	1639	1847
Growth (%)	20.6	48.2	38.6	4.9	12.7
EPS	63.6	94.3	130.7	137.1	154.5

#### **Balance Sheet**

As at March	FY19	FY20	FY21E	FY22E	FY23E
SOURCE OF FUNDS					
Share Capital	24	24	24	24	24
Reserves	5415	6137	7367	8623	10033
Shareholders' Funds	5439	6161	7391	8647	10057
Long Term Debt	231	159	131	112	79
Long Term Provisions & Others	214	232	263	279	303
Minority Interest	133	148	169	169	169
Total Source of Funds	6017	6700	7954	9209	10611
APPLICATION OF FUNDS					
Net Block & Intangibles	2599	2848	2912	3012	3165
Goodwill	380	373	373	373	373
Deferred Tax Assets (net)	768	975	995	1025	1070
Long Term Loans & Advances	215	251	308	358	417
Total Non-Current Assets	3962	4447	4588	4769	5025
Current Investments	228	170	192	213	252
Inventories	1500	1819	1910	2069	2253
Trade Receivables	1248	1649	1669	1831	1979
Cash & Equivalents	662	1092	1962	2767	3478
Other Current Assets	535	720	770	805	890
Total Current Assets	4204	5498	6545	7715	8889
Short-Term Borrowings	671	1504	1308	1148	1045
Trade Payables	962	955	992	1183	1258
Other Current Liab & Provisions	430	602	668	714	750
Short-Term Provisions	127	185	210	229	250
Total Current Liabilities	2149	3245	3178	3275	3303
Net Current Assets	2055	2254	3367	4441	5586
Total Application of Funds	6017	6700	7954	9209	10611



#### **Cash Flow Statement**

(Rs Cr)	FY19	FY20	FY21E	FY22E	FY23E
Reported PBT	955	1260	1828	1962	2270
Non-operating & EO items	-88	-104	-139	-154	-169
Interest Expenses	55	65	73	67	63
Depreciation	193	253	277	298	327
Working Capital Change	-298	209	-254	-287	-435
Tax Paid	-181	-110	-238	-292	-386
OPERATING CASH FLOW (a)	636	1572	1547	1594	1670
Capex	-547	-457	-330	-380	-480
Free Cash Flow	89	1115	1217	1214	1190
Investments	12	-236	-77	-81	-104
Non-operating income	88	104	139	154	169
INVESTING CASH FLOW ( b )	-447	-589	-268	-307	-415
Debt Issuance / (Repaid)	149	-55	3	-1	-8
Interest Expenses	-55	-65	-73	-67	-63
FCFE	183	995	1148	1145	1119
Share Capital Issuance/MI	11	15	21	0	0
Dividend	-229	-319	-361	-413	-473
FINANCING CASH FLOW ( c )	-124	-423	-410	-482	-544
NET CASH FLOW (a+b+c)	65	560	870	805	711

#### **Key Ratios**

Rey Natios						
	FY19	FY20	FY21E	FY22E	FY23E	
EBITDA Margin	15.2	17.7	22.5	21.5	22.2	
EBIT Margin	12.5	14.6	19.5	18.6	19.3	
APAT Margin	10.5	13.8	17.6	16.5	16.8	
RoE	14.8	19.4	23.1	20.4	19.7	
RoCE	13.8	14.9	19	18.1	18.6	
Solvency Ratio						
Net Debt/EBITDA (x)	0	0.3	-0.4	-0.8	-1	
D/E	0.2	0.3	0.2	0.1	0.1	
Net D/E	0	0.1	-0.1	-0.2	-0.3	
PER SHARE DATA						
EPS	63.6	94.3	130.7	137.1	154.5	
CEPS	79.8	115.4	153.9	162	181.9	
BV	454.9	515.3	618.2	723.3	841.3	
Dividend	16	25	30	34	39	
Turnover Ratios (days)						
Debtor days	62	72	67	66	64	
Inventory days	73	73	77	75	73	
Creditors days	80	78	72	77	75	
VALUATION (x)						
P/E	43.5	29.4	21.2	20.2	17.9	
P/BV	6.1	5.4	4.5	3.8	3.3	
EV/EBITDA	29.6	22.4	16.2	15.2	13.2	
EV / Revenues	4.3	3.8	3.5	3.2	2.8	
Dividend Payout (%)	25.1	26.5	23	24.8	25.2	
Source: Company, HDFC sec Res						

Source: Company, HDFC sec Research



#### **One Year Price Chart**





#### Disclosure:

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