

### Ind-Swift Laboratories Limited: High margin complex chemical synthesis

### Key strengths

- High margin API player leveraging strong research skills in complex chemistry
- Global leadership in key products
- USFDA approved facilities
- Reliable supplier to domestic as well global formulation players
- Global reach presence in more than 50 countries including large markets of USA and Japan through strategic alliances and tie-ups
- Research capabilities, manufacturing scale and regulatory approvals makes preferred partner of global pharmaceutical companies for CRAMS.

### Future road map

- Increasing API product range through leveraging research skill for complex chemistry
- Creating global scale of key high value products going off-patent in next 2-3 years
- Enhancing global reach by increasing geographical presence.
- More product registrations for regulated markets mainly for complex products.
- Continuously tapping long term CRAMs opportunities through strategic alliances with global players.

### **Contents**

- Corporate identity 02 Vice-Chairman and MD's statement 04 Corporate information 21 Directors' Report 22 Management discussion and analysis 28
- Report on Corporate Governance 30 Financial Section 43

# Ind Swift Labs Ltd. is placed attractively on the growth curve.

Aptly demonstrating our capability to usher in growth in good times and bad, by proactively investing in our intellectual capital, core infrastructure and longstanding client relationships to build on our foundation of strength.

Growth in regulated markets.

Growth in certified capacities.

Growth in product portfolio and pipeline.

Growth in R&D infrastructure.

Growth in resident intellectual capital.

Growth in customer base.



### **Products**

Ind Swift Labs has emerged as one of the largest manufacturers of APIs and advanced intermediates. Ind Swift Labs has prudently selected to be present in 16 therapeutic segments, of which five comprise sustained use therapies (cardiology, diabetology, oncology, anti-depressant and anti-hyperlipidemic). Its product portfolio comprises 40 APIs that are marketed in India and in the International markets. Of the product basket, 8 APIs pertain to sustained-use therapies. The Company is fully integrated and leading global manufacturers of Clarithromycin/granules, Atorvastatin, Fexofenadine, Clopidogrel and Nitazoxanide.

### **Parentage**

Ind Swift Laboratories Ltd. (Ind Swift Labs) is a part of the Rs. 2000 crores Ind Swift Group, headquartered in Chandigarh, India. The Company was set up in 1995 by Ind Swift Ltd., a leading manufacturer of Finished Dosages Form. Ind Swift has emerged as a single largest shareholder, holding now 27.16% equity in Ind Swift Laboratories Ltd.

### Presence

Ind Swift Labs markets its products in strategic partnership with two distinct client categories: respected Indian finished dosage manufacturers with a large global exposure and to those in Soft to Regulated Markets, the former accounting for 59.5% of the turnover and the latter 40.5%

### Performance

Ind Swift Labs has grown its topline in each year of its existence. Revenue grew at a CAGR of 25.57% over the last five years, while profits increased at a CAGR of 13.65% during the period.

### Public holding

In 2009-10, the Company's shares were listed on the Mumbai, National and Luxembourg Stock Exchange and enjoyed a market capitalization of Rs 186.27 cr as on 31st March 2010.

### **Plants**

Ind Swift Labs has invested prudently in relevant assets, equipment and infrastructure. It possesses 19 manufacturing blocks located at Derabassi, Patiala (Punjab) and Samba, Jammu (J&K)-designed to manufacture products from basic stage and to comply with stringent USFDA and cGMP standards. The Company possesses a cumulative reactor capacity of 370 TPA, one of the largest in India. The Company's competitive edge has been reinforced with a sophisticated State of the art R&D centre manned by more than 100 scientists, again one of the largest of its kind in the region for API development.

### Groundwork for growth

Turnover

Rs 783.55 cr

Growth of 35.18% over 2008-09

PAT

Rs 57.96 cr

Growth of 39.6% over 2008-09

EBIDTA margin 18.83%

Cash profit

Rs 96.22 cr

Growth of 31.36% over 2008-09

Exports

40.40%

Growth of 46.11% over 2008-09

"Our business strategy has been a reconciliation of value and volume growth, a lower-than-industry conversion cost and higher-than-industry value addition."

Operationally the year 2009-10 was a good one: operational revenue grew by 35 per cent, profit after tax than 46 per cent, an increase in our market capitalisation by more than 184 per cent and a

intense competition and a stronger rupee, I see the improvement as a watershed in our history and a vindication of our business model, firmly establishing that the Company is on a growth trajectory.

Before seizing this opportunity to enumerate the intrinsic reasons for our optimistic performance, there were myriad external reasons that have influenced the Company's prospects and will continue to do so over the foreseeable future. Amongst the key markets outside the United States and Europe, the Japanese market offers potential to drive significant growth in the medium term. With healthcare reforms aimed to reduce healthcare budgets and genericfriendly policies being adopted by the Japanese Government, the pharmaceutical market is gradually opening up to generics. The current generic penetration in Japan, estimated at 6-7%, is amongst the lowest in the world. As a result, despite being the second largest pharmaceutical market in the world, the Japanese market ranks only as the sixth largest generic market. The Japanese Government has set a target of reaching a generic penetration of 30% by 2012, implying strong growth potential in the market. The Japanese pharmaceutical market is characterised by a complex regulatory framework, thereby creating a high entry barrier. Thus, partnerships with local generic companies and/or acquisitions of local companies are emerging as the likely route to gain presence. Ind-Swift is also making inroads in this market through various partnerships

Generic business by its nature grows at the expense of branded products on patent expiry, bringing in potential conflict of interest between the two. Ind-Swift continues to seek ways to accelerate entry into the market through development of non-infringing processes/ patent

challenges, innovator companies seek to extend their product life through effective patent defense. In recent times, the pressure on innovator companies has increased due to large impending patent expiries and shrinking new product pipelines.

Noting the large patent expiries over the next five years and weak pipeline quality of Innovator Companies have increased the pressure on innovator companies to explore other avenues including generic business. While the global pharmaceutical business is expected to register moderate single digit growths, the growth in generic business is likely to be in double digits, reflecting the attractive potential of the business. Some of the global innovator companies already have their generic arms which are aggressively pursuing the business in all markets. In recent periods, a number of innovator companies have explored alliances and M&A in the generic space. In recent periods some of the innovator companies have entered into alliances with Indian generic companies. These alliances are designed to exploit the low-cost manufacturing skills of Indian players with the reach of innovator companies in the branded generic space across world markets.

With innovator companies focusing on cost rationalisation. outsourcing opportunities across the value chain -from low volume drug discovery activities to higher volume commercial scale manufacturing- have emerged over the past few years. Ind Swift is in the process of establishing relations with several innovator companies as a precursor

increased in excess of 39 per cent, export jump of more proposed dividend for our shareholders. Considering that this improvement came in the face of

Annual Report 2009-10 | 5 4 Ind-Swift Laboratories Ltd.

Vice- Chairman and MD's statement

to scaling up this business, which also entails significant investments in manufacturing and R&D capabilities. Innovator companies typically look for strong R&D capabilities and human resources as the key criteria while selecting contract research companies, while the ability to ensure low-cost manufacturing is seen as their key strength.

### **Initiatives**

At Ind Swift, we undertook all necessary actions to be on the growth track. While we consolidated our footprints in high-growth and regulated markets such as the US, we also focused on emerging markets and the domestic space. We have undergone various internal re-orientations to evolve as the preferred supply chain partner, with an eye on robust infrastructure and enhanced R&D practices.

A mature market presence: We expect to expand in global markets by continuous addition of new products and increasing the strategic partnerships with the leading players. We also expect to strengthen our export exposure in fully regulated markets by 2014.

Focused product development: We will continue to focus our product development creation of novel platform

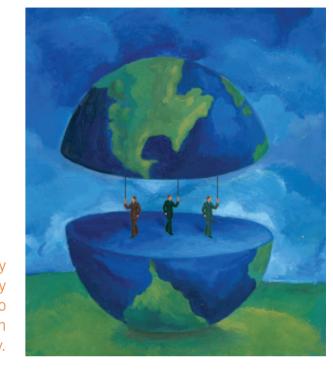
technologies possessing the cost and the capacity impact.

**Evolution of product mix:** We have selectively evolved our product mix towards high growth therapeutic segments catering to lifestyle diseases. As a result of this focus, revenues from lifestyle therapeutic groups are expected to grow substantially over the next five years.

Pioneering launches: Over the years, the Company has maintained its position of being among the first three in the country and among the first five in the world to launch a majority of complex products. This translated into attractive margins and shorter payback, allowing us to invest horizontally (new product development) and vertically (capacity expansion).

Launch of new products: We expect to grow our basket of 40 products to around 80 over the next five years with an eye on patent expiry in the US and Europe. Around 6-7 products will be launched in the current fiscal.

At Ind Swift, we realize that serving customers through the well-defined service portfolio, including post-shipment technical assistance, protecting the quality and responsiveness of this service in accordance with client feedback is the cornerstone of our success. Providing an



We also conscientiously invested in eco-friendly manufacturing practices to make further investments in our sustainability.

enjoyable work environment to catalyse intellectual capital growth through a global employment of skills, established culture of meritocracy and institutionalization of systems has also been pivotal in our growth path.

Over the years, Ind-Swift Laboratories long-term optimism has been reflected in the selection of assets that were not only contemporary when they were commissioned but which have remained so over time. By increasing our operational scalability in line with globally benchmarked standards has fared well for the Company across the long-term. We expanded the production capacity of various products to meet the growing demand. We are also continuously upgrading our systems and processes to adhere to the new stringent USFDA and cGMP standards.

We also conscientiously invested in eco-friendly manufacturing practices to make further investments in our sustainability.

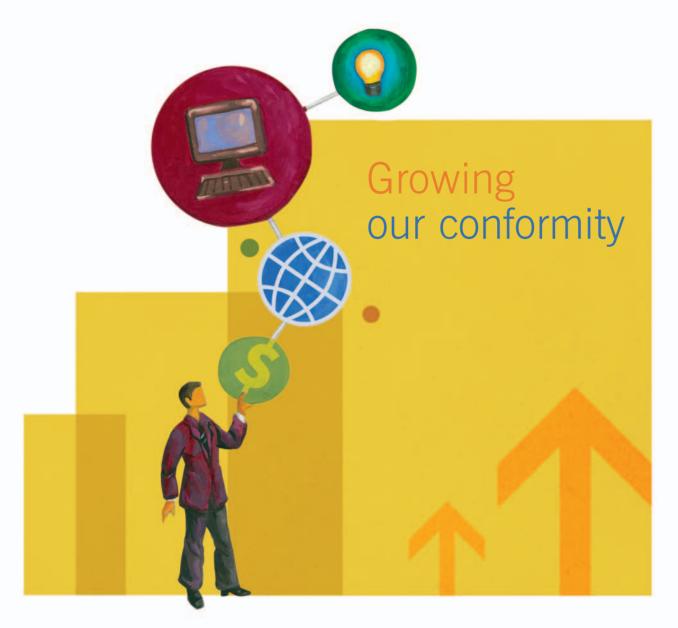
Although the current environment is challenging, but at the same time it throws up several new opportunities for the Ind-Swift. What worked in the past may not necessarily hold them in good stead in the future. We have taken cognizance of the fundamental changes the industry is going through and re-jig our strategies accordingly and will be able to successfully navigate the future.

Our business strategy has been a reconciliation of value and volume growth, a lower-than-industry conversion cost and higher-than-industry value addition. In doing so, we expect to report robust margins over the coming years. Ind Swift Laboratories expects to emerge as one of the most profitable pharmaceutical companies in India, enhancing value for the user, consumer, community and shareholder.

Signed

N. R. Munjal

Vice Chairman and Managing Director



In recent times, the global pharmaceutical industry has shown high interest in India due to its sustained economic growth, health care reforms. In the last few years Indian pharmaceutical industry has achieved significant momentum, making its presence felt in the global market primarily through its focus on global generics markets.



Ind Swift Labs has been able to successfully establish itself in more than 50 countries across the globe

Ind Swift is conveniently placed, with the advantage of cost competitiveness, ability and experience in reverse engineering, availability of skilled scientific and engineering personnel and the capability to produce raw materials for a wide range of drugs from the basic stage.

The Indian generic manufacturers are expected to grow at a faster clip as drugs worth approximately US\$ 20 bn in annual sales will face patent expiry in 2011. Nearly US\$ 80 billion worth of patent-protected drugs will go off-patent (including 30 of the best selling US patent-protected drugs) by 2012-13. The generic penetration in Europe has increased manifold over last 7 years. UK which is second largest market in EU has grown by 2 times during last 7 years. Europe's generics market is expected to over US\$30 billion in 2011-12.

With intent to consolidate its presence in the international scene and become a preferred business partner for reputed international pharmaceutical corporates, Ind Swift Labs embarked proactively on taking the following steps:

■ Made substantial investment in capacities over the last three years in preparation of regulated market foray

- Commissioned all manufacturing facilities in alignment with the cGMP which is recognised and accepted in the stringent regulated markets like USA, Europe, Australia and Japan
- Enlisted itself with internationally renowned associations
- Commissioned an R&D centre in Mohali at an investment of Rs 25 cr with 100 qualified professionals In doing so,
- Ind Swift Labs filed more than 288 DMFs across the globe in the CTD format.
- It is among the first few Indian companies to file DMFs in a number of European countries in 2009-10 alone
- It has been able to successfully establish itself in more than 50 countries across the globe

Commenced the supply of commercial quantities to the United States. Currently, the Company exports three products commercially to the United States: Clarithromycin (started in 2007) and Ropinorole (started in November 2008) and Naratriptan (in 2009-10) besides the export of development quantities of over 7-8 products.

Growing

our capacities

At the point of selection of a supplier or service provider, more emphasis is placed on the levels of infrastructure, training facilities, scalability, quality standards, service delivery, process capability, and the comparative rates of employee turnover.

A key critical aspect of selection process is the ensuring alignment of the culture and values of both the partners. This is crucial as far as process transition is concerned. These are also key areas that affect not only the choice of service provider, but the shape of ongoing governance. The quality of the due diligence visits and the composition and capability of the due diligence teams to cover both operational and strategic aspects of the relationship will ensure a quality decision.

Faced with increasing cost and commercialization pressures, global pharmaceutical companies are looking at how to tap India's fast-growing domestic market and provide a 'faster and cheaper' value proposition in terms of manufacturing and R&D. The hope inside India is that the country's pharma firms can replicate the success of its Business Process Outsourcing (BPO) companies as preferred international partners, both in terms of competitive costs and world-class capabilities. One key is the important transition already underway in some Indian pharmaceutical firms as they shift from developing imitative drugs to also focusing on innovation.

To accelerate this change, India's pharmaceutical industry needs to ensure that its current 'faster and cheaper' value proposition is sustainable and scalable.

Keeping this reality in view, Ind Swift Labs has undertaken the following initiatives:

- In the last four years, ISLL has cumulatively invested around Rs. 2,760 million towards capacity expansion for existing products, setting up of new plants (modules at Derabassi and Jammu Plant) and R&D centre at Mohali:-
- 1. In 2006-07, the capex was directed largely at the Mohali R&D centre.
- 2. The capex in 2007-08 was towards the menthol facility at Derabassi, an anti-cancer plant, capacity expansion and balancing equipment at existing Derabassi and Jammu manufacturing facilities.
- 3. In 2008-10, the capex was directed towards capacity expansion, balancing equipment at existing facilities and

setting up of London office.

- Of its manufacturing plants, few are dedicated to certain products and the others are for multiple purposes.
- The capital expenditure programmes for the Company in 2010-11 include setting up a multipurpose plant for manufacturing of APIs and a 4.6 MW coal-based captive power plant, alongwith the enhancement of capacities.
- In 2009-10, the Company added capacities for its seven to eight of its existing products such as Fexofenadine (added 18 TPA), Clarithromycin granules (added 48 TPA), Clopidogrel (added 12 TPA), Clopidogrel intermediates (added 6 TPA), Atorvastatin (6 TPA).
- The Company has also commissioned a new facility for Nitazoxanide with a capacity of 30 TPA
- The Company commissioned an 8.5 ton boiler in 2009-10 at Derabassi, which will lead to an enhancement in production capacity. The Company had installed capital equipment requiring more steam, the demand of which can easily be met with the steam generated by the boiler
- ISLL has converted utilities using power-generating systems with steam-generated systems, leading to a reduction in operating costs to a great extent

As a result,

- The Company is expected to continue its capacity expansion as it plans to file 4-5 DMFs a year and entering the highly lucrative therapeutic segments of Oncology,
- Its production volumes of API increased 40% over the previous year.
- Its production volumes of Menthol related products also increased substantially.
- It forged alliances with reputed international pharmaceutical companies for servicing their requirements of four primary APIs-Clarithromycin, Fexofenadine, Atorvastatin and Clopidogrel-exclusively from the Company once they go offpatent



Ind Swift Labs' production volumes of API increased 40% over the previous year.

## Growing our portfolio



With the growth in US and developed economies expected to decline, emerging economies like India are expected to drive future growth. The key growth drivers in these countries are increasing per capita income, growing insurance penetration, better health awareness, higher government expenditure, adherence to IPR norms and shift in disease profiles.

Indian companies are well positioned to partake of this huge domestic opportunity. Indian companies need to broaden their product portfolio to include growing therapeutic segments such as anti-diabetics, central nervous system and cardiovascular. Companies can now sell premium products to aspiring Indian middle and high class, while at the same time continue their focus on low value but high volume bottom of the pyramid class.

ISLL is involved in the manufacturing of APIs and advanced intermediates. The Company derives more than 30% of its revenues from macrolides-a class of antibiotics. Clarithromycin is a second generation macrolide with the largest revenue contribution. Atorvastatin (cardiovascular) and Fexofenadine (anti-allergy) are the other key products of the Company.

ISLL currently has a portfolio of 40 products including drugs like Clarithromycin (macrolide anti-biotic), Atorvastatin (anti-cholestrol), Fexofenadine (anti-histamine), Clopidogrel (anti-cholestrol), Nitazoxanide (anti-diarrheal), Pioglitazone (anti-diabetic), Letrozole & Anastrozole (anti-cancer), Venlafaxine (anti-depressants), Quetiapine & Aripiprazole (anti-psychotic), Donepezil( Alzhiemer disease) and Naratriptan( Anti-Migrane).

Ind Swift responded to industry reality in the following manner:

■ During the year, the Company launched new drugs like Cinacalcet, Duloxetine, Mecloxamine citrate, Atomoxetine, Exemestane, Ezetimibe, Pregabalin, Ranolazine, Telmisartan and Posaconazole. The other products driving the growth of the Company are Letrozole, Anastrozole (Anti-Cancer) Venlafaxine

(Anti-Depressants) Levofloxacin (Anti-Biotic) Quetiapine & Aripiprazole (Anti-Psychotic) Ezetimibe (anti-hyperlipidemic) and Pioglitazone, an anti-diabetic drug.

- The Company is further developing newer products such as Dutasteride, Argatroban, Gefitinib, Eletriptan & others.
- The Company has increased its range of APIs in the Domestic market with the successful introduction of new products like Ivabradine and Cinacalcet for which Ind Swift Labs is the first and only Company to launch the products in the Indian Market.
- It selected to manufacture complex APIs with high entry barriers, hazardous reactions and involving large working capital requirements
- Clarithromycin contributed more than 19% of the total sales of the Company in 2009-10. The dependence on old products has reduced over the last four to five years through addition of new products to its portfolio.
- Atorvastatin is the second largest product of ISLL. The Company derives more than 80% of the revenues for this product from exports to Eastern Europe and Latin America, given the basic product patent protection for this product in the United States until 2010.
- Fexofenadine emerged as the third largest product for ISLL in 2009-10, with more than 50% of sales realised from exports.



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### Growing our research base



The key to growth for Indian companies in the pharmaceutical business, today, are a formidable research and development pipeline, a significantly broader portfolio of medicines and an expanded presence in key international markets, particularly in high growth emerging markets. The global consolidation may trigger optimization of assets both in manufacturing and research thus affecting the future business of contract service providers.

Strategic tie-ups with global companies offer several opportunities for Indian companies to create 'win-win' situations, particularly in R&D. R&D divisions of Indian pharma companies have started making the move from reverse engineering to development of new molecules.

Over the years, Ind-Swift has strengthened its R&D through the following initiatives:

Pledge: Ind Swift Labs invested Rs 261 cr in the last ten years towards its R&D initiative, approximating 33% of its annual turnover in 2009-10.

**Strength:** The Company R&D strengths comprised niche chemistry skill sets, with specialized expert talent pool of scientists and technical personnel.

Capability: it developed an expertise model for the development of the stable management of complex techniques and processes (chiral separations, Grignard reaction, Stetter reaction, Silylation, Oximation, Ketallisation, Hydrogenation under pressure, Beckmann rearrangement and stereoselective synthesis).

Equipment: It invested in sophisticated world-class equipment capable of handling extreme reactions involving a temperature range from - 1500C to +2500C and pressure capacity upto 15 kg/sq. inch. R&D is fully equipped with state of the art analytical equipments comprising several HPLCs, LCMASS, GCMASS, DSC, XRD and several other equipments.

Partnership: It entered into a tie-up with reputed academic institutes facilitating an easy access to critical insights

**International:** It is continuously upgrading its R&D infrastructure at par with international standards

**Bio batch plant:** The Company has installed a bio-batch plant, operating as per cGMP norms, facilitating the approvals of its products in the international and domestic markets.

Facility: The Company's Rs 70 cr and 40000 sq. ft. state-of-the-art R&D centre at Mohali, comprises eight synthetic labs (five generic, the rest dedicated for contract research for international majors), the latest equipment and gadgets to facilitate development of non-infringing processes, helping generate data as per ICH guidelines and prepare DMFs in CTD format for US and other regulated markets.

In doing so, the Company:

- Filed over 80 DMFs in 2009-10; taking the total count to 288 DMFs
- The number of patents filed during the year also increased to 145 as on March 2010.
- Launched several new molecules through in-house research, a majority launched within a year in India of their launch by the innovator Company, belonging to the top 10 therapeutic groups
- Emerged as the first in the world to develop Clarithromycin granules and the first to develop Roxithromycin granules.
- Possesses a Research and Development, Chemical Research and Analytical Development facility duly recognized by the Department of Science and Technology (Government of India)
- Possesses an attractive pipeline of 20 products expected to go off-patent by end of 2010
- Undertook process optimisation and improvements for molecules in 2009-10 such as the following
- Donepezil Hcl-Process for improving residual solvents contents to meet current regulatory needs as well as a process for robust polymorph formation.
- Ropinirole-Process to control impurity formation during crystallization.
- Nateglinide-Process for consistency of Polymorph formation at large scale.
- Process developed for the following molecules in 2009-10-Eletriptan HBr.(API), Dutasteride (API), Raloxeifene (API), Bexarotene (API), Prasugrel Hcl (API), Dapoxetin (API), Colesevelam (API), Ketoconazole (API), Temozolamide (API)
- Developed non-infringing processes for molecules including Eletriptan HBr, Raloxifene, Temozolamide and Olmesartan in 2009-10
- Undertook pilot studies for Cinacalcet HCL (API), Telmisartan (API), Ezetimibe (API), Prasugrel and Colesevelam in 2009-10
- Commercialised the production of Donepezil (Alzheimer's Disease), Nateglinide (Anti Diabetic), Naratriptan (Anti Migrane) and Risedronate (Osteoporosis) in 2009-10
- Developed a key intermediate of Quetiapine
- Possesses an attractive pipeline of products including Aripiprazole, Montelukast, Adefovir, Saxagliptin, Sunitinib, Rosuvastatin and Ertapenem as on March 2010.

Growing

our intellectual

capital



The pharmaceutical industry is facing increased pressure from shortening new product development times, from escalating research costs, and from governmental reforms aimed at constraining healthcare costs. In this climate, companies depend on their ability to discover, develop and market innovative products faster and more effectively than the competition.



Production per employee increased by 47%, while profit per employee strengthened from Rs 4.40 lakhs to Rs 5.85 lakhs in 2009-10

The pharmaceutical industry perhaps relies more than any other on innovation and the efficient transfer of knowledge. When knowledge management is tied directly to critical business processes, it can deliver remarkable benefits. In the pharmaceutical business, people are knowledge banks who drive profitability, making it imperative to retain them.

Ind Swift labs has attracted and retained the best talent within the industry through the following initiatives:

- Team: The Company created a 3 member team for career profiling and competency mapping to ensure that the right person is recruited for the right job
- Knowledge: It focused on knowledge-enhancement through an institutionalized training (hard and soft skills) calendar that covered all employees.
- Investment: it invested Rs 30 lakhs in training programmes
- Training: It ensured that each person got alteast four days of Training per year .
- Meritocracy: Migrated to a culture of incentive-linked performance pay structure
- The Board also allotted 670,000 options to employees under Employee Stock Option Plan (ESOP).
- Quality of life: The Company inducted a culture of work life balance, where employees were encouraged to avail 50% of their leaves and special care was taken to reduce overtime
- Defining: Role and job clarity was introduced and institutionalized and employees were made clearer of their roles and responsibilities

- Outlining: Competency mapping to ensure that gaps in the skills needed for upward mobility in the Organizational Hierarchy could be filled through enhancement of responsibilities on the current function.
- Appraisal: KPI's-based appraisal forms were introduced to ensure more reliability in appraisal of employees
- Key employees were identified and given fast track promotions keeping in view their good service record with Company.
- Automation was initiated at every level and is treated as a continuous exercise to reduce casual manpower improve efficiency/productivity and increase profit per employee

The main HR Initiative that transpired in the year under review was to carry out a detailed exercise to enhance role clarity and role expectations covering the entire Derabassi manufacturing facility. This entailed mapping out all the positions again with a focus on enhancing clarity regarding the skill sets required to do the job well and the alignment of responsibilities and duties with each position.

Employees were involved to make the system more effective through Project 'Junoon', which was launched to reduce wastage and collect valuable suggestions from employees.

As a result,

■ Production per employee increased by 47%, while profit per employee strengthened from Rs 4.40 lakhs to Rs 5.85 lakhs in 2009-10