



Incepta Pharmaceuticals Limited

ACHIEVEMENT OF EUROPEAN GMP CERTIFICATE

Special Supplement :

Friday, March 14, 2008



Adviser
Ministry of Health and Family Welfare
and
Ministry of Food & Disaster Management
Govt. of the People's Republic of Bangladesh

MESSAGE

I am happy to learn that Incepta Pharmaceuticals Ltd. has achieved 'Certificate of GMP Compliance' from European Commission. This will be considered as a milestone in the export-oriented pharmaceutical sector of Bangladesh. I congratulate all the members of Incepta family for this great achievement. The Government has already declared pharmaceutical sector as a 'thrust sector' by realizing its potentiality. We want to capture the highest benefit of this potentiality and hence we have no scope of compromise with the quality of medicine. I hope, many other pharmaceutical companies of the country will be inspired by the glorious achievement of the Incepta Pharmaceuticals Ltd.

I wish Incepta Pharmaceuticals Ltd's greater success.

Shawkat
Dr. A M M Shawkat Ali



Director
Directorate of Drug Administration
and Licensing Authority (Drugs)
Govt. of the People's Republic of Bangladesh

MESSAGE

I am very much pleased to know that Incepta Pharmaceuticals Ltd has received 'Certificate of GMP Compliance' from European Commission. This certification will set a new milestone for the Pharmaceutical industry of our country. I came to know that Incepta is the first national company to achieve such recognition. This achievement will certainly pave the way of export of locally manufactured medicines to the European countries. Our local pharmaceutical companies meet about 97% of the national demand of medicines. I hope in very near future our local industry would be able to meet almost 100% of the national demand. We emphasize on manufacture of high quality medicines by strictly following GMP guidelines at all levels. Receipt of EU certification by Incepta is the result of our continuous effort in increasing the quality of medicines for both the local and the export markets. I believe this is a matter of pride for not only Incepta but a reflection of quality of local medicines as a whole. We are likely to become a major supplier of low cost generic medicines to the whole world and it is a matter of time only before we reach such status. In this auspicious moment I congratulate all the members of Incepta Pharmaceuticals Ltd for achieving this certification.

Sarkar
Brigadier General Sarkar M A Matin

European GMP Certification: New Era in Pharma Business

Incepta Pharmaceuticals Limited has made the history as the first Bangladeshi company to have the European GMP Certification. It is not only the breakthrough for Incepta, it is also the recognition of our growing Pharmaceuticals Industries.

Medicine is an essential item and we are very lucky to have attained almost self sufficiency in supplying this vital product to the people of Bangladesh. Majority of the developing countries and almost all LDCs except Bangladesh depend on imported medicines. The progress of our pharmaceutical industry is quite commendable and it is now becoming a major source of medicines for the whole world. The global pharmaceutical market was about 608 billion dollars in 2006 as reported by IMS. North America enjoys the largest market share followed by Europe. The distribution of sales by region along with their respective market growth is shown in the following table. The total market in the developed countries is mainly divided into two different broad categories namely; branded drugs and generic drugs. Branded drugs are usually patented and are marketed by the innovator company. Generic drugs are copy of the innovator brands and are introduced only after expiry of patent life of the brand. During past decade patents for many products with large market share expired. The copies of those products are now available as generic drugs at fractional costs. The brand companies are facing increasingly difficult task of introducing innovative new products. The introduction of new molecule has drastically fallen in recent past because of the inability of the research based companies to find out new effective treatment options. This has caused more and more mergers and acquisitions among large brand companies. Companies are trying to survive by combining their compatible R&D pipeline and also by reducing their operational cost. Hoechst was the largest company of the world in 1984 but that company does not exist anymore. While the big brand companies are finding it difficult to introduce new molecules, the innovations did not stop and are thriving in different fields. New treatment options are coming in huge numbers from biotech and vaccine companies. New biological products and therapeutic vaccines with more targeted treatment approach are becoming the principal armament of tomorrow's treatment. These products are highly expensive and will become the main business of the brand companies. Dr. Steve Arlington, principal author of a report published by Price Water House Coopers predicted that the global pharmaceutical market will be about US\$ 1300 billion in 2020. The production base for the small molecule generic drugs is slowly shifting to the developing countries. In fact the process has started long ago with the shifting of API (Active Pharmaceutical Ingredient) production initially to Spain and Italy and now to India and China. At present China has become the major supplier of API intermediates to the whole world. The generic formulation products are now increasingly supplied by India. The present market for generic medicines is about 50 billion US dollars. The market for North America is about 35 billion and that of European Union is about 15 billion USD. The major generic companies are Teva, Sandoz/Novartis, Watson, Barr etc. These

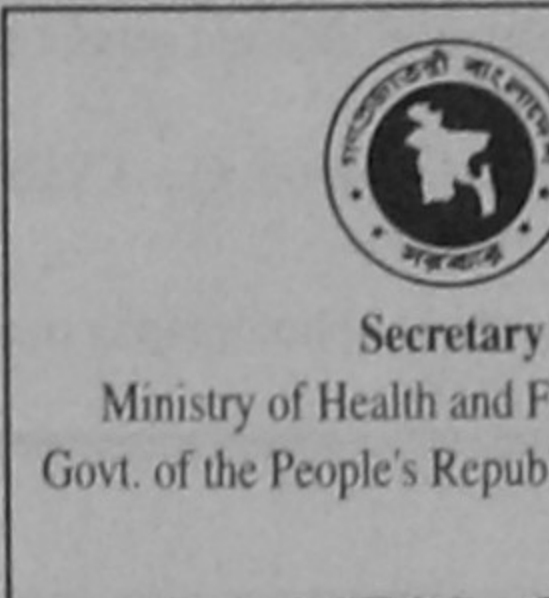
companies are enjoying excellent growth because of patent expiry of increasing number of blockbuster brand products. The generic business is no safe heaven for the upcoming generic industry as they experience spiraling reduction of prices of generic drugs with the introduction of the same drug by many competitors. This has caused tremendous pressure to even established generic manufacturers. This is where the opportunity is created for the low cost manufacturers from the developing world.



More and more companies from the west are looking for reliable contract manufacturers in India and other English speaking countries as most of the voluminous documents are done in English. European GMP compliance certification for Incepta Pharmaceuticals Ltd has opened a new era for Bangladesh as it provides the opportunity for Incepta to enter into the vast 15 billion dollar EU market. The company has already started

getting orders from as many as 15 EU countries. All these orders are primarily of site transfer type which involves manufacturing of a particular product which is currently manufactured in another approved site. This kind of transfer is taking place because it is cheaper to manufacture the drugs in Bangladesh compared to other manufacturing sites. The company is now making alliance with other partners in order to be able to come forward with its generic products. This will require completion of bioequivalence studies for the potential products. Once several products are ready then those products will not only be sold in Europe but will also gain market access to vibrant Middle Eastern, Russian and South American markets. Introduction of Incepta's products to EU market will open up various other opportunities namely backward integration to API and other ingredients manufacturing, bioequivalent studies etc. The industry must be prepared to manufacture API with European Drug Master File (EDMF) as these materials are found to be about 2 to 3 times more expensive than pharmacopoeia standard material. Bangladesh will find it very difficult to compete with other developing countries unless the companies start manufacturing their own EDMF standard API. The pharmaceutical sector of Bangladesh is making steady progress and it is widely believed that the industry will be overcome all the hurdles in a short span of time. Bangladesh needs few more business sectors to come forward in order to diversify its export as well as to avoid its over-dependence in the garment industry. Pharmaceutical sector can contribute significantly in increasing the export from Bangladesh. The government has proved its eagerness to support pharma industry by declaring it as a thrust sector. The international trade in medicine requires lots of documentation and inspection by the regulatory body. The government now needs to strengthen the regulatory body with increased manpower having proper education, skill and training in order to be able to handle increased work load for export. The pharmaceutical sector is marching forward and Bangladesh will soon be able to tell yet another success story of bright industry.

World Audited Market	2006 Sales (US\$Bn)	% Global Sales	% Growth Year-over-Year (Constant US\$)
North America	\$289.9	47.7%	8.0%
Europe	181.8	29.9%	4.8%
Japan	56.7	9.3%	-0.7%
Asia, Africa and Australia	52.0	8.6%	9.8%
Latin America	27.5	4.5%	12.9%
Total IMS Audited	\$607.9	100%	6.5%

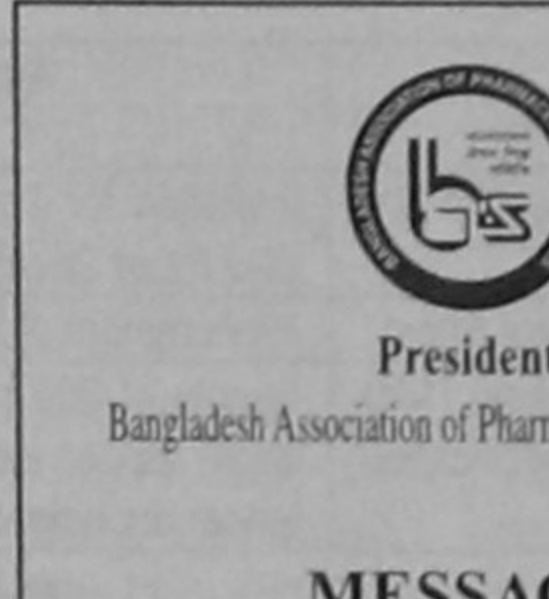


Secretary
Ministry of Health and Family Welfare
Govt. of the People's Republic of Bangladesh

MESSAGE

I am glad to know that "Incepta Pharmaceuticals" has received "Certificate of GMP compliance" from European Commission. Certainly, it is a great achievement. This achievement will certainly help the pharmaceutical industries to take its products to the prestigious regulated markets like EU, USA, UK etc. Bangladesh will be able to establish itself in the area of supplying high-tech pharmaceuticals to the global market. For the achievement, I convey my heartiest congratulations and well wishes to all the members of the "Incepta Pharmaceuticals".

Zafar
A K M Zafar Ullah Khan



President
Bangladesh Association of Pharmaceutical Industries

MESSAGE

It is a matter of great pleasure to be informed that Incepta Pharmaceuticals Ltd. a leading and promising pharmaceutical company received the GMP Certification from European Commission. Indeed, this is a matter of great honor for our total Pharma industry. European Commission Certification has the potentiality to significantly increase export of medicines of Bangladesh origin to not only Europe but also in many other countries. The local pharmaceutical industry is currently able to meet about 97% of the country's total demand. Some vaccines and anti-cancer drugs are imported now and these medicines are regarded to be very expensive. In future these medicines will also be manufactured locally and the prices will certainly come down. After meeting local demand our pharmaceutical companies export both finished drugs and API to more than 67 countries in the world. After getting GMP certification from EC, we shall now be able to enter into many other regulated markets. I convey my cordial facilitation to the members of Incepta Pharmaceuticals Ltd. for such achievement and also wish for their success in future.

Shafuzzaman
S M Shafuzzaman

Incepta Pharmaceuticals-Domestic to Global Presence

Incepta, a Bangladeshi pharmaceutical company, is committed to improve health and enhance quality of life. Since 2000, this organization is striving to meet the positive impact on people's lives through developing and marketing innovative products in Bangladesh. The name, derived from 'Innovative Concept into Practice', reflects its commitment to focus the need of our people, research and development to bring innovative products to the communities it serves. At Incepta Pharmaceuticals Limited, we operate with a vision of developing, formulating and commercializing leading innovative and essential pharmaceutical products to prevent and treat the diseases and enhance the quality of life of people. Incepta Pharmaceuticals Limited, one of the leading pharmaceutical company of Bangladesh established its pharmaceutical plant at Savar, 35 kilometers away from the center of the capital city Dhaka. The plant underwent further expansion in phases to meet both domestic & export opportunities of generic pharmaceuticals to many countries. Apart from regular inhouse audit, the Plant experienced its first international inspection by UN organization in 2005 for supply of pharmaceutical products for the domestic market and the next international audit by AGES, the regulatory inspection authority of Austria in November 2007 for export approval to EU countries. In the meantime Incepta ensured its global presence by making footprint in Guyana, Afghanistan and Togo in 2006. In 2007 there was phenomenal growth in Incepta's export market. Incepta was able to export its products to 19 countries throughout the world including Asian, African and Central American countries.

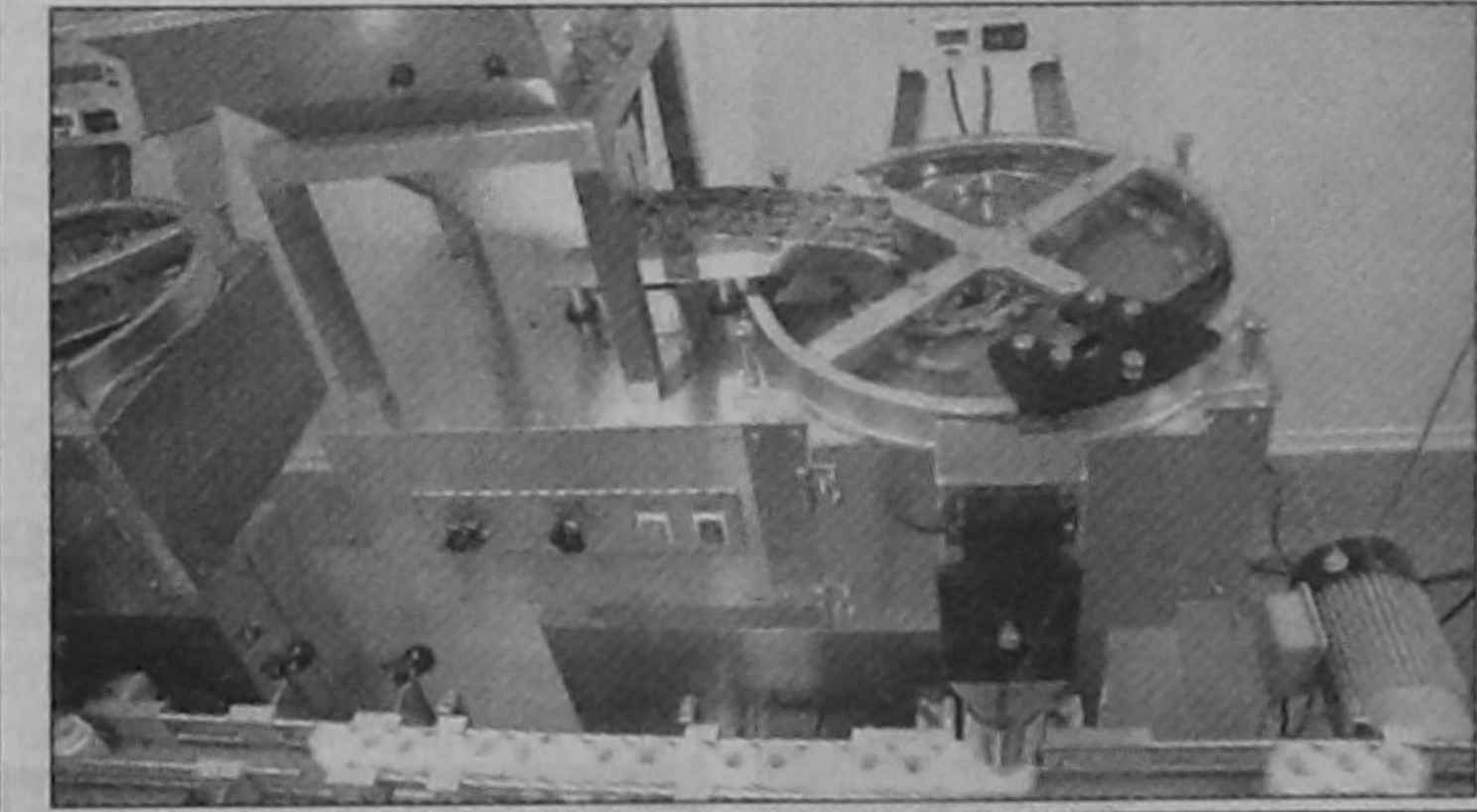
Subsequently in January 2008, it received the European Certification for Good Manufacturing Practices (GMP). This gave Incepta Pharmaceuticals Limited the export opportunities to Europe, South America and other global regulated market destinations on a mutual recognition system. As an outcome of this successful achievement, Incepta Pharmaceuticals Limited will become the first Bangladeshi company to make the export of generic pharmaceuticals to western European markets from Bangladesh. Because of this global quality adherence by Incepta pharmaceuticals plant, the domestic market end users are greatly benefiting from the availability of international quality standard pharmaceutical products at a very affordable price. Further this is the company which is pioneer for bringing many new molecules first time ever in Bangladesh market. In order to keep up the achieved standard of quality, Incepta Plant under takes series of different quality management activities to sustain the supply to the European and other regulated markets, in addition to the non-regulated markets. These measures are taken according to the international standard of Pharmaceutical Inspection Convention (PIC) and Pharmaceutical Inspection Co-operation Scheme, more precisely known as PICs. Export forecast shows the products to be supplied from Incepta factory will increase substantially over the next few years and eventually to about 70 countries. Anticipating higher orders in the years to come, Incepta will then be one of the major exporters of pharmaceuticals from Bangladesh as well as a major exporter generally. It will also make an impact to put forward the "Made in Bangladesh" on a global base and establish the good image for the country.



Incepta's Contribution to the Bangladesh Pharmaceutical Sector

Incepta Pharmaceuticals Ltd. is currently the third largest manufacturer of Pharmaceuticals in Bangladesh. After establishment in the year 1999, Incepta went into production in the month of January 2000. With a modest beginning in that year Incepta was ranked 35th among more than 225 companies of the country. A unique trend was set from the very first year of operation as Incepta made its presence felt in the market with its very unique products. Products that were in high demand and required very high technology investment and only available in the developed country were introduced in the local market by Incepta. Incepta called these products the first ever products launched in the Bangladesh Pharmaceutical market. In order to improve the quality of life of the people Incepta has so far introduced to the market 193 brands with 490 dosage forms. Following in the footsteps of Incepta many other companies also introduced similar brands at a later time. Currently the company is heavily investing in more value adding high knowledge and technology based products targeted towards fulfilling the dream of achieving self sufficiency in medicine manufacturing. Once achieved, this will go a long way to improve the quality of life of the people through availability of these products at an affordable price. Products like Insulin, Enoxaparin, Erythropoietin, Lyophilized injectables, Effervescent Tablets, Nasal Sprays, dedicated cephalosporin facility for all the cephalosporin products are all examples of such investment in both knowledge and technology. Although a relatively new company Incepta has already achieved several milestones like approval of European standard, enlistment as supplier of UN organization etc. That are adding glory to the sector as well for the country. We are now a leading manufacturer of high quality generics and bio-generics in Bangladesh. Our network of distribution offices supplies products to all corners of the country. Our exports have already reached five continents

and we are on the verge of entering high value and highly regulated market. The core value that drives Incepta is to embrace global quality standards in all its operations. Incepta currently employs more than 2700 people directly in its different operations throughout the country. Highly skilled and educated workforce forms the bulk of this people. Pharmacists, Doctors, Engineers, Microbiologists, Biochemists, Accountants and Science Graduates of different disciplines comprise more than 60% of this workforce creating huge employment opportunity. While the emphasis is always on taking fresh people in all possible areas the company is generating tremendous employment opportunities for highly skilled people through continuous investment in knowledge and technology based expansion projects. Incepta has proved itself to be a very solid performer in all spheres of its operation and as recognition to its achievements Incepta was awarded 'The Enterprise of the Year 2004' award in 2005. Incepta contributes significantly to the national exchequer every year. It strictly follows the rules of the land and therefore has already earned the respect of the stakeholders. Incepta a manufacturer from Bangladesh faces tremendous challenge with the harsh realities of the world market. The relatively small local base coupled with our lack of investment in both knowledge and technology makes any vision of becoming a global company a daunting task. However, Incepta is determined to overcome all odds and set a very ambitious vision to become a research based global pharmaceutical company in addition to being highly efficient generic manufacturer. Also to discover and develop innovative, value-added products that improves the quality of life of people around the world. Also significantly contribute towards the growth of Bangladesh. With the achievement of European certificate on 11th January 2008 Incepta is now better prepared to take the challenge of the world.



Incepta At a Glance

Profile: Incepta Pharmaceuticals Ltd is a fast growing pharmaceuticals design from manufacturing company. Incepta develops, manufactures and markets medicines to address the unmet medical needs of both Bangladesh and foreign markets.

Type of Company: Private Limited

Incorporation: February, 1999

Production: January, 2000

Position in Industry: 3rd (IMS report)

Production Facility: 300000 Sq. feet

Total Employee: 2715

Total Products: 193 generics

490 presentations

Specializations: Value added high technology dosage form like

- Sustained release tablets and injection
- Quick mouth dissolving tablets
- Barrier coated delayed release tablet
- Lyophilized injection

R&D Facility: The facility has the same specification as that of production area and is equipped with all kinds of production equipments. The facility is also fully equipped for stability study and analytical method development.

Beginning of Export: July, 2006 (3 countries)

Number of exporting countries: 19 (up to 2007)

Factory Address: Devan Idris Road, Bara Ranganata, Zinda, Savar, Dhaka. Tel: 7708502-6

Head office address: 40 Shohid Tashfin Ahmed Sarwar, Tejgaon I/A, Dhaka. Tel: 8378111-26

Distribution and sales offices: 14 (Dhaka, Chittagong, Rajshahi, Khulna, Barisal, Rangpur, Comilla, Sylhet, Mymensingh, Narayanganj, Magura, Cox's Bazar, Noidahali, Bogra)

Incepta Pharmaceuticals Limited: Present and the Future

Incepta Pharmaceuticals Ltd. is a fast growing pharmaceuticals dosage form manufacturing company established in the year 1999. The company has a very big manufacturing facility located at Savar, 35 kilometers away from the center of the capital city Dhaka. The company produces all types of dosage forms such as tablet, capsule, liquid, dry suspension, granules in sachets, liquid injections in ampoules, powder vials for injection, lyophilized vials for injection, eye drops, large volume injections in PVC bags and vials, pre-filled syringes etc. Incepta began its market operation in January 2000. From then onwards Incepta has been

launching new and innovative products at a faster pace. By the end of 2007 it has already launched 193 generics with a total of 490 presentations. The focus was to bring more new and technologically advanced products to this country. During the last 8 years of operation Incepta launched as many as 93 new generics for the first time ever in Bangladesh and this number is by far the highest number of new products introduced by any single company. This has required huge investment in the area of Research and Development as each new product had to be developed with detail work on formulation, quality control and stability. The

company specializes in value added high technology dosage forms like sustained release tablets and injections, quick mouth dissolving tablets, barrier coated delayed release tablets, lyophilized injections etc. It has established a modern research and development laboratory for the development of new advanced dosage forms for various drugs and devices like poorly soluble drugs, dry powder inhalers, coated pellets, modified release products, taste masked preparation, depot injections etc. The company is now expanding its R&D facility to a new area and the work will be completed by June 2008. The facility has the same specification as that of the production area and is equipped with all kinds of production equipments suitable for production of tablets, capsules, lyophilized injections etc. The facility is also fully equipped for stability study and analytical method development. Incepta quickly developed a very competent sales team, which promotes the specialties throughout the country. The company virtually covers every single corner of the rural as well as urban area of Bangladesh. It has its own large distribution network having 14 depots all over the country. The company has a clear vision to become a leading research based dosage form manufacturer with global presence within a short period of time. The company has been achieving robust growth and became the third largest company

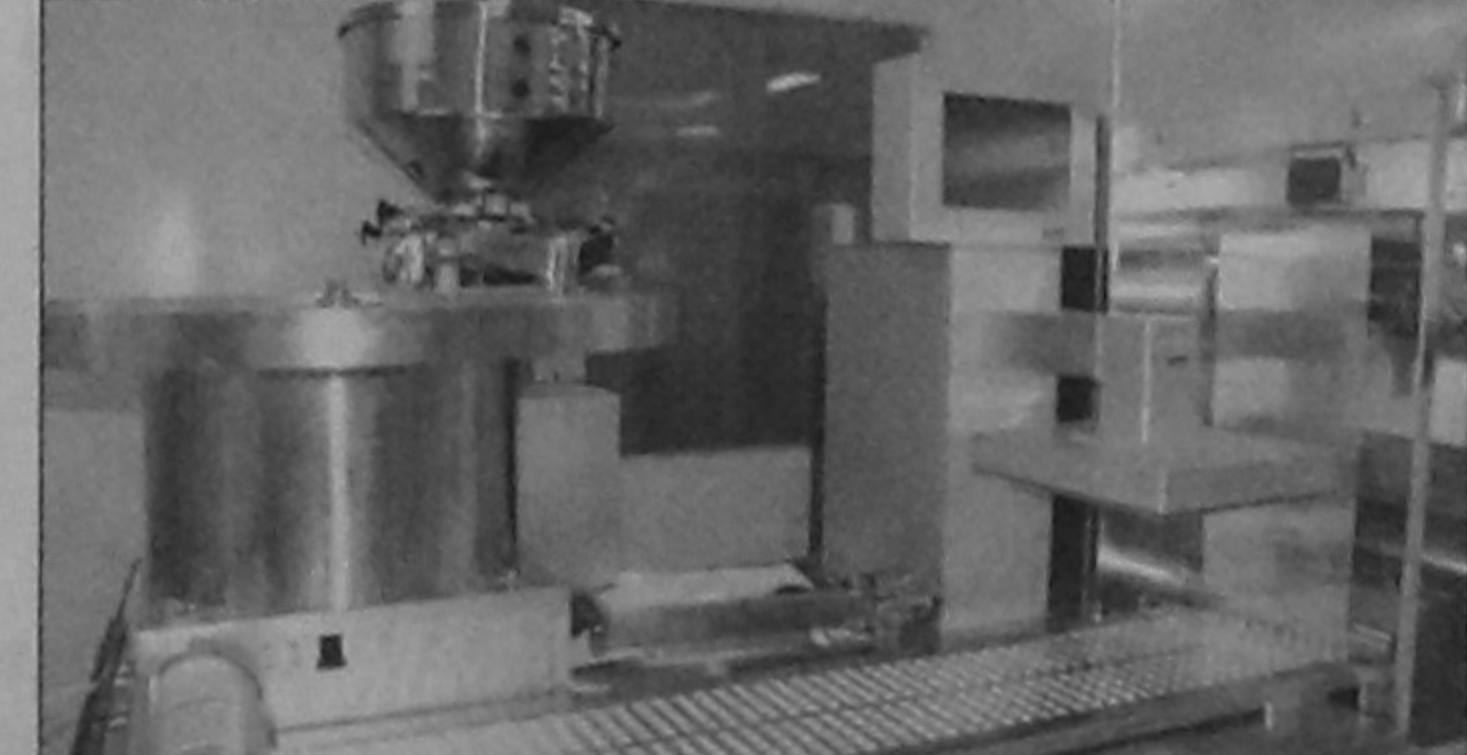
among 200 companies within a span of 6 years of operation. Incepta started registering its products for export only in 2005 and by now has become successful to export to as many as 19 different countries spanning all 5 continents. Registration is going on in another 25 countries. The export growth has been phenomenal and is likely to be more in future. Achievement of European GMP certificate is yet another successful step which will increase export significantly to Europe and other regulated markets. Incepta is planning to achieve rapid growth both at home and abroad. The growth will come from the following three areas: a) Introduction of technologically advanced products b) Export to both regulated and non-regulated markets c) Production of Active Pharmaceutical Ingredient (API). We have already started manufacturing various technologically advanced products like erythropoietin, insulin, enoxaparin etc and this trend will continue. The company will introduce more biotech products and other advanced dosage forms. Exports to developing countries are growing and we will take initiative to export our products to as many countries as possible. Incepta has set up its own marketing teams in several countries and its brands are becoming popular among the doctors. More marketing offices will be opened in various countries to establish Incepta brands in those

countries. We are also making alliances with different companies in different countries to increase export from Bangladesh. Export to developed markets is currently planned through site transfer of existing products. We are taking initiative to register our own products in EU. This will require bioequivalence studies and preparation of registration dossiers in CTD format. Young intelligent pharmacists are being trained in global regulatory affairs so that they can prepare and submit dossiers worldwide. We are finding it difficult to compete with regional companies because of higher prices of API with

Drug Master File (DMF). Therefore Incepta has initiated to establish a reverse engineering lab as well as a facility for production of API. This will help us develop and manufacture our own API. After completion of these future plans Incepta will become a major player in global generic medicines. The country has plenty of qualified people who would be able to manufacture medicines at competitive prices. With the initiative of Incepta and other leading pharmaceutical companies, Bangladesh will soon emerge as a giant medicine exporting country.



Abdul Muktar, Managing Director, Incepta Pharmaceuticals Limited



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Managing Director
- Hasneen Muktar**
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- Zahiruddin Mahmud**
Executive, Director
- Md. Enayet Husain Siraj**
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- Reaz Ahmed Khan**
Director
- A Rashid Majumdar**
Director
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- Faridur Reza Sagar**
Director