

All Your Ingredients In One Magazine

Ingredients

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NITIKA

TABCELL

MICROCRYSTALLINE CELLULOSE

101 / 102 / 112 / 200 / RS 591

The Right Cellulose.



More Excipients

- | | | | |
|--|--|---|--|
| ■ TABLUBE
Magnesium Stearate | ■ NOVALUBE
Sodium Stearyl Fumarate | ■ PHARMAPEG
(400 / 3350 / 4000 / 6000 / 8000)
Polyethylene Glycol | ■ TABGLIDE
Purified Talc |
| ■ COLNAT
Iron Oxide
(Red/Yellow/Black/Brown) | ■ ACILUBE
Stearic Acid Powder | ■ SPECHE
Iron Stearate,
Manganese Stearate
Cobalt Stearate | ■ TABFIL
Dibasic Calcium
Phosphate |
| ■ TABSTAR
Pregelatinized Starch | ■ TABELLOSE
HPMC E-5,6,15,
K-4, K-100M | ■ HYPROMALATE
HPMC Phthalate | |



In Far East, coop ventures are in

DR SANJAY AGRAWAL

BASED on production volume of APIs (Active Pharma Ingredients), India ranks among the top five nations, accounting for approximately 8.5 per cent of global production. The turnover increased from US\$ 0.33 billion in 1980 to US\$18.2 billion last year. However, the world market value is US\$ 53 billion. This growth is supported by low costs of skilled human resources, innovation, and other factors.

In the Far East countries that include South East Asia like Malaysia, Indonesia, and a few parts of Russia, the growth of the pharmaceutical industry and its market size is ever increasing. There is a dependency on the other API producing countries, yet, a significant up-growth is observed. These countries have witnessed a healthy growth over the last five years, and the different government sectors well fuel it. Some tight price control policies do not provide much freedom in pricing branded products. The government is yet to increase the share of locally produced drugs and encourage the local industry's expansion.

India is the third-largest in APIs, while China is the main competitor. India's API industries include both domestic and international consumption, as well as exports. The API manufacturers in India are working to increase their market share in regulated markets. They do this using different methods, such as process modification and increasing production yields, especially for critical products.

On the East side of the world, the manufacturing standards comply with numerous international regulations. Due to technological advances, many Indian manufacturers have entered highly-regulated markets in America and Europe.

What is the current status?

The first step in pharmaceutical manufacturing is transforming raw materials into APIs. These are important because they comprise a large portion of the drug's total cost (40-50%). The World Health Organization (WHO) defines API as any substance or combination used in a pharmaceutical product. It can be intended to provide pharmacological activity or directly affect the treatment, diagnosis, mitigation, treatment, prevention, or restoration of human physiological functions. API production is a complex, complicated, and challenging process that involves biochemical, chemical or fermentation processes. This process is used in the global pharmaceutical industry. In Malaysia, Indonesia and Japan, there is one big corporation, pharma, and the rest is dependent on China's

production of APIs.

The three largest Indonesian pharmaceutical companies are the largest importers of raw materials. This change will help them meet the rising demand for medical insurance. Vidjongtius is a Jakarta-based director of Kalbe Farma, Indonesia's largest drug company. He stated in an interview that transactions in Indonesian rupiah would be possible if raw materials were locally manufactured. Removing foreign investment restrictions could reduce dependence on imports of raw materials to make drugs. It also may ease the demand for dollars that are more costly due to a weaker rupee in the last year.

In a separate interview with Reuters, Yaser Arafat, Indofarma's corporate secretary, said, "In Indonesia currently, there isn't a basic chem-



ical industry that supports the development and production of raw materials. We became complacent because it was easier to import. It's better to be late than never."

In 2014, Indonesia introduced a universal healthcare program that is phasing in. This has shaped the demand for drugs and made it difficult to meet local manufacturing requirements. About 90% of Indonesia's API requirements are imported, mostly in dollars.

Kendrariadi Suhanda (group secretary of the Indonesian Pharmaceutical Association) stated in April that to reduce dependence on imports for APIs and other raw materials, the domestic industry requires investments of over \$1 billion.

Russia plans to conquer API production

As Russia, Ukraine, and the Baltics increase their pharmaceutical manufacturing capabilities, the production of active pharmaceutical components will migrate from China and India. PMR, a market analyst, says that drugmakers are still looking for API sources after the 2007-2008 contaminated heparin case, in which the deadly substance was traced back to China.

API production in Russia and Ukraine and contract manufacturing of finished dosage products

In-Pharma Technologist reports that the \$1.3 billion federal programs to develop the pharmaceutical industry in Russia will be a significant driver for 2020. The program includes a promise by Vladimir Putin, Russian President, to construct 200,000 sq m of production facilities for sterile and nonsterile pharmaceutical production. The plan has one weakness: it does not include GMP standards. Russia must implement GMP widely to persuade companies that they want to purchase APIs from Russia over India or China.



Global API producers

There are over 2,000 API manufacturers and more than 5,000 production sites worldwide. This makes the API market very competitive. Several major API producers in the US and EU produce special APIs that share a significant portion of the global market. Many API manufacturers are located in Asia, particularly India and China. As a result, more pharmaceutical companies are outsourcing API manufacturing to these countries.

Merck, AstraZeneca and GlaxoSmithKline, Teva Active Pharmaceutical Ingredients (TAPI), Dr Reddy's Laboratories, Aurobindo, Cipla, Sandoz, Sandoz-Lek-Biochemie, Ranbaxy, Matrix, Sun Pharma, BASF SE, Fabbri Italiana Sintetici, GlaxoSmithKline, Pfizer CentreSource, Royal DSM and Zhejiang Hisun Pharmaceutical Co. Ltd., are the leading API manufacturers in the world. Joko Widodo, the Indonesian president, has allowed foreign companies to acquire 100% of API operations. This eliminates the requirement that a local partner is present at 85%.

To conclude, Asia, Europe, and North America are the top three exporters of API goods, with a combined export share of 87.4% for bulk pharmaceuticals. More than 1,500 different types of API products are produced in China, with a capacity of about two or three million tonne. As a result of concerns posed by more recent market entries to the established small and medium-sized manufacturers and the resulting high level of competitiveness, mergers and collaborations are currently the methods used in the worldwide API sector. In Far East countries, the respective companies are now establishing cooperative ventures to share technology to produce API medications to solve these difficulties. ○

(The author is a leading pharmaceutical consultant)