Active Pharma Ingredients (API) Amoxicillin Trihydrate, Azithromycin & Paracetamol

<table>
<thead>
<tr>
<th>Capacity</th>
<th>Paracetamol : 1,000.0 Kgs / day Azithromycin: 500.0 Kgs / day Amoxicillin Trihydrate: 500.0 Kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plant and machinery cost:</td>
<td>175.00 Lakh</td>
</tr>
<tr>
<td>Working Capital:</td>
<td>0.00 Lakh</td>
</tr>
<tr>
<td>Rate of return(ROR):</td>
<td>29.00 %</td>
</tr>
<tr>
<td>Break Even Point (BEP):</td>
<td>47.00 %</td>
</tr>
<tr>
<td>TCI:</td>
<td>0.00 Lakh</td>
</tr>
<tr>
<td>Cost of Project:</td>
<td>1322.00 Lakh</td>
</tr>
</tbody>
</table>
Active pharmaceutical ingredients are the active substances that are used in the manufacture of a drug and have a pharmacological effect. They provide health benefits and play a vital role in disease diagnosis, prevention, and treatment. Active pharmaceutical ingredients may be synthesized either chemically or through biotechnological methods.

Azithromycin is used to treat certain bacterial infections, such as bronchitis; pneumonia; sexually transmitted diseases (STD); and infections of the ears, lungs, sinuses, skin, throat, and reproductive organs.

Paracetamol is a commonly used medicine that can help treat pain and reduce a high temperature (fever). It is often recommended as one of the first treatments for pain, as it's safe for most people to take and side effects are rare. India is the seventh largest country in the world and has the second highest population. It has a parliamentary democratic form of government and has abundant natural resources and sufficient oil reserves.

Huge investment promises from different countries predict a bright future for India. It has a well-developed administration and an independent judicial system with an ever-growing consumer base. It has a huge pool of hard-working skilled workers in all fields. The government has set up tax and non-tax incentives to establish new industrial entities in specific sectors, which include energy, ports, highways, electronics, and software. The Make in India initiative was launched by the government in 2014 and received an excellent response from the developed nations. The government has also created special areas dedicated to export, called export-processing zones (EPZs) or special economic zones (SEZs), to encourage foreign investment.

The global active pharmaceutical ingredient market size is expected to reach a value of USD 286.6 billion by 2027, registering a CAGR of 6.7% over the forecast period. Factors, such as increasing preference for outsourcing APIs and growing prevalence of various target diseases such as cancer and Cardiovascular Diseases (CVDs) are expected to drive the market growth.

Patent expirations of blockbuster drugs give rise to generic versions of these molecules, wherein the manufacturers bear the cost. After a patent expires, R&D investments done by the company are no longer beneficial for the company. API production requires a huge capital amount as the process needs extremely systematic protocols. Thus, pharmaceutical companies benefit from outsourcing API production, as it eliminates the need for labor force and installing expensive manufacturing units. Strategic outsourcing allows companies to focus on their core competencies, ultimately resulting in increased productivity. These factors are also projected to drive the active pharmaceutical ingredient market growth.

The growth of active pharmaceutical ingredients market is marked by the huge demand for drugs like analgesics, anti-infectives and diabetes, and pain management drugs. But with the rising trend of increasing research and development (R&D) activities, the demand is experiencing a shift towards the advancement of complex APIs that find use in novel formulations, thereby targeting niche therapeutic areas. This facilitates the development of new technologies and ensures a high quality product.

Among the problems for pharmaceutical supply chains during this pandemic are the restrictions and impact of COVID-19 on two of the largest global producers of active pharmaceutical ingredients (APIs) and generics: China and India.

APIs is a crucial part of the pharma industry’s strategic plan to combat the COVID-19 pandemic. The majority of APIs for generic drug manufacturing across the globe are sourced from India, which also supplies approximately 30 percent of the generic APIs used in the US. However, Indian manufacturers rely heavily on APIs from China for the production of their medicine formulations, procuring around 70 percent from China, the top global producer and exporter of APIs by volume.

**Role of Government towards API**
The coronavirus outbreak disrupting supply of active pharmaceutical ingredients (APIs) and medical devices from China to India, the government has come out with four schemes worth Rs 13,760 crore to encourage manufacturing of bulk drugs and medical devices in the country and their exports.

On March 21, the Union Cabinet under the chairmanship of Prime Minister Narendra Modi had approved an expenditure of Rs. 9,940 crore and Rs. 3,820 crore for APIs and medical devices, respectively.

The Cabinet also approved a scheme on promotion of bulk drug parks for financing common infrastructure facilities in three bulk drug parks with financial implication of Rs. 3,000 crore for next five years. The government will give grants-in-aid to states with a maximum limit of Rs. 1,000 crore per bulk Drug Park. Parks will have common facilities such as solvent recovery plant, distillation plant, power and steam units, common effluent treatment plant etc.

The government further approved production linked incentive (PLI) scheme for promotion of domestic manufacturing of critical KSMs/drug intermediates and APIs in the country with financial implications of Rs. 6,940 crore for next eight years.

Financial incentive will be given to eligible manufacturers of identified 53 critical bulk drugs on their incremental sales over the base year (2019-20) for a period of 6 years.

Out of 53 identified bulk drugs, 26 are fermentation based bulk drugs and 27 are chemical synthesis based bulk drugs.

Rate of incentive will be 20 per cent (of incremental sales value) for fermentation based bulk drugs and 10 per cent for chemical synthesis based bulk drugs.

The PLI scheme will lead to expected incremental sales of Rs. 46,400 crore and significant additional employment generation over eight years.

The drug industry has welcomed the incentives offered by the government to promote API units in India.

Besides APIs, the Cabinet also approved the scheme for promotion of medical device parks in the country in partnership with the states. A maximum grant-in-aid of Rs. 100 crore per park will be provided to the states. It will have financial implications of Rs. 400 crore.

The PLI scheme for promoting domestic manufacturing of medical devices will have financial implications of Rs. 3,420 crore for next five years.

Medical device is a growing sector and its potential for growth is the highest among all sectors in the healthcare market. It is valued at Rs. 50,026 crore for 2018-19 and is expected to reach to Rs. 86,840 crore by 2021-22. India depends on imports up to an extent of 85 per cent of total domestic demand of medical devices.

Union Cabinet scheme on Promotion of Bulk Drug Parks

• The scheme on Promotion of Bulk Drug Parks for financing Common Infrastructure Facilities in 3 Bulk Drug Parks with financial implication of Rs. 3,000 crore for next five years.

• Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical KSMs/Drug Intermediates and APIs in the country with financial implications of Rs 6,940 crore for next eight years.

Details:

Promotion of Bulk Drug Parks

• Decision is to develop 3 mega Bulk Drug parks in India in partnership with States.

• Government of India will give Grants-in-Aid to States with a maximum limit of Rs. 1000 Crore per Bulk Drug Park.

• Parks will have common facilities such as solvent recovery plant, distillation plant, power & steam units, common effluent treatment plant etc.

• A sum of Rs. 3,000 crore has been approved for this scheme for next 5 years.

Production Linked Incentive Scheme

• Financial incentive will be given to eligible manufacturers of identified 53 critical bulk drugs on their
incremental sales over the base year (2019-20) for a period of 6 years.

- Out of 53 identified bulk drugs, 26 are fermentation based bulk drugs and 27 are chemical synthesis based bulk drugs.
- Rate of incentive will be 20% (of incremental sales value) for fermentation based bulk drugs and 10% for chemical synthesis based bulk drugs.
- A sum of Rs. 6,940 crore has been approved for next 8 years.

**Few Indian major players are as under**

Alpha Remedies Ltd  
Ankur Drugs & Pharma Ltd.  
Cian Healthcare Ltd  
Farmson Pharmaceutical Gujarat Pvt. Ltd.  
Glaxosmithkline Pharmaceuticals Ltd.  
Pan Drugs Ltd  
Piramal Enterprises Ltd.

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