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

<table>
<thead>
<tr>
<th>Capacity:</th>
<th>Paracetamol: 1,000 Kgs / day</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Azithromycin: 500 Kgs / day</td>
</tr>
<tr>
<td></td>
<td>Amoxicillin Trihydrate: 500 Kgs / day</td>
</tr>
</tbody>
</table>

| Plant and machinery cost: | 175.00 Lakh |
| Working Capital:          | 0.00 Lakh   |
| Rate of return (ROR):     | 29.00 %     |
| Break Even Point (BEP):   | 47.00 %     |
| TCI:                      | 0.00 Lakh   |
| Cost of Project:          | 1322.00 Lakh |
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.

The Active Pharmaceutical Ingredient (API) is the part of any drug that produces the intended effects. Some drugs, such as combination therapies, have multiple active ingredients to treat different symptoms or act in different ways.

Active Pharmaceutical Ingredient (API), is the term used to refer to the biologically active component of a drug product (e.g. tablet, capsule). Drug products are usually composed of several components. The aforementioned API is the primary ingredient. Other ingredients are commonly known as "excipients" and these substances are always required to be biologically safe, often making up a variable fraction of the drug product. The procedure for optimizing and compositing this mixture of components used in the drug is known as "formulation."

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. The country has a huge skilled, English-speaking, and inexpensive labor force. Its young population and current economic policies have made it one of the largest recipients of FDI in the world. 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.

Majority of specialty API companies are increasing their manufacturing facilities for specialty active pharmaceutical ingredients (API) to take care of or gain market share. Substantial investments within the growth of approved specialty active pharmaceutical ingredients (API) is one in all the most important factors among key players in the specialty active pharmaceutical ingredients (API) market.

For instance, in early 2020, Wuxi STA opened oligonucleotide API manufacturing facility in Changzhou, China to cope up with the increasing demand.

In 2018, Cordon Pharma expanded operations with new commercial oligonucleotide active pharmaceutical ingredients (API) manufacturing capabilities at its FDA inspected Colorado facility.

The emergence of COVID-19 has brought the world to a standstill. We perceive that this health crisis has brought an unprecedented impact on businesses across industries. However, this too shall pass. Rising support from governments and several companies will help within the fight against this highly contagious disease. There are some industries that are struggling and some are thriving. Overall, almost each sector is anticipated to be impacted by the pandemic.

**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 Rs6,940 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.
Aurobindo Pharma Ltd.
NIIR Project Consultancy Services (NPCS) is a reliable name in the industrial world for offering integrated technical consultancy services. Its various services are:

Pre-feasibility study, New Project Identification, Project Feasibility and Market Study, Identification of Profitable Industrial Project Opportunities, Preparation of Project Profiles and Pre-Investment and Pre-Feasibility Studies, Market Surveys and Studies, Preparation of Techno-Economic Feasibility Reports, Identification and Selection of Plant and Machinery, Manufacturing Process and or Equipment required, General Guidance, Technical and Commercial Counseling for setting up new industrial projects and industry. NPCS also publishes various technology books, directory, databases, detailed project reports, market survey reports on various industries and profit making business. Besides being used by manufacturers, industrialists and entrepreneurs, our publications are also used by Indian and overseas professionals including project engineers, information services bureau, consultants and consultancy firms as one of the input in their research.

NIIR PROJECT CONSULTANCY SERVICES
106-E, Kamla Nagar, New Delhi-110007, India.
Tel: 91-11-23843955, 23845654, 23845886, +918800733955
Mobile: +91-9811043595
Email: npcs.ei@gmail.com ,info@entrepreneurindia.co
Website: www.entrepreneurIndia.co