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Investment Opportunities in APIs-KSMs-



Bulk Drug Industries.



Cabinet Approves Promotion of Domestic

Manufacturing of Critical Key Starting

Materials-Drug Intermediates and

Active Pharmaceutical Ingredients

in the Country.



Introduction

Key Starting Materials (KSMs)/Drug Intermediates

KSMs from the <u>essential</u> medicines list for strategic reasons posed by the COVID-19.

Role of Government Towards (KSMs)/Drug Intermediates

The Union Cabinet chaired by the Prime Minister, Shri Narendra Modi has approved the following schemes:-

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/<u>Drug Intermediates and APIs</u> 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 <u>India</u> 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, <u>power</u> & steam units, common effluent treatment plant etc.
- A sum of Rs. 3,000 crore has been approved for this scheme for next 5 years.
- Related Projects: <u>Pharmaceutical</u>, <u>Drugs</u>, <u>Fine Chemicals</u>, <u>Bulk Drug</u> <u>Intermediates</u>,



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 <u>chemical</u> synthesis based bulk drugs.
- Rate of incentive will be 20 % (of incremental sales value) for fermentation based bulk drugs and 10% for <u>chemical</u> synthesis based bulk drugs.
- A sum of Rs. 6,940 crore has been approved for next 8 years.





Impact:

Promotion of Bulk Drug Parks:

The scheme is expected to reduce manufacturing cost of bulk drugs in the country and dependency on other countries for bulk drugs.

Production Linked Incentive Scheme:

- The scheme intends to boost domestic manufacturing of critical KSMs/Drug Intermediates and APIs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/Drug Intermediates and APIs.
- It will lead to expected incremental sales of Rs. 46,400 crore and significant additional employment generation over 8 years.



Implementation:

Promotion of Bulk Drug Parks

The scheme will be implemented by State Implementing Agencies (SIA) to be set up by the respective State Governments and the target is to set up 3 mega Bulk Drug Parks.

Production Linked Incentive Scheme

The scheme will be implemented through a Project Management Agency (PMA) to be nominated by the Department of <u>Pharmaceuticals</u>. The Scheme will be applicable only for manufacturing of 53 identified critical bulk drugs (KSMs/<u>Drug Intermediates and APIs</u>).

Related Books: - Pharmaceutical, Drugs, Proteins Technology

Handbooks



Benefits:

- Common <u>infrastructure</u> facilities would be created with the financial assistance under the sub-scheme in 03 Bulk Drug Parks.
- It is expected to reduce manufacturing cost and dependency on other countries of Bulk Drug in the country.

Related videos: - <u>Manufacturing Business Ideas in Pharmaceutical</u>
<u>Industry</u>

Manufacturing of Pharmaceutical Bulk Drugs and Medicine

Pharmaceutical Pellets and Granules

Pharmaceutical Manufacturing Unit

Indian Pharma Industry: An Investment Opportunity

Manufacturing Business Ideas in Pharmaceutical Industry



List of Critical KSMs/Drug Intermediates and APIs

Fermentation Based 04 KSMs/Drug Intermediates and

Corresponding APIs

- 1. Penicillin G/6-Amino Penicillinc Acid (6-APA)
- 2. Cephalosporin C/7-Amino Cephalosporanic Acid (7-ACA)
- 3. Erythromycin Thiocyanate/TIOC
- 4. Potassium Clavulanate





Fermentation Based 10 Niche KSMs/Drug Intermediates and

Corresponding APIs

- 1. Cyclins (Tetracycline, Oxycycline, Doxyxcline)
- 2. Aminoglycosides (Gentamycin)
- 3. Aminoglycosides (Neomycin)
- 4. Aminoglycosides (Streptomycin)
- 5. Steroids (Betamethasone)
- 6. Steroids (Dexamethasone)
- 7. Steroids (Prednisolone)
- 8. Anti TB (Rifampicin)
- 9. Vitamins and Nutraceuticals (Vitamin B6)
- 10. Vitamins and Nutraceuticals (Vitamin B1)



Chemical Synthesis Based 04 KSMs/Drug Intermediates and

Corresponding APIs (with backward integration)

- 1. Dicyandiamide (DCDA)
- 2. Para-aminophenol
- 3. 2-Methyl -5 Nitro- Imidazole (2-MNI) including Imidazoles.
- 4. 1, 1 Cyclohexane Diacetic Acid (CDA)





Other Chemical Synthesis Based 23 KSMs/Drug Intermediates

and Corresponding APIs (with backward integration)

- 1) Levofloxacin
- 2) Sulfadiazine
- 3) Ciprofloxacin
- 4) Ofloxacin
- 5) Norfloxacin
- 6) Artesunate
- 7) Telmisartan





7)	Telmisartan
8)	Losartan
9)	Valsartan
10)	Olmesartan
11)	Atorvastatin
12)	Acyclovir
13)	Lopinavir
14)	Ritonavir
15)	Oxcarbazepine
16)	Carbamazepine





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17)	Levodopa
18)	Carbidopa
19)	Levetiracetam
20)	Aspirin
21)	Diclofenac Sodium
22)	Tinidazole
23)	Ornidazole





Market Outlook

The Indian <u>pharmaceutical industry</u> is the 3rd largest in the world by volume. However, despite this achievement, India is significantly dependent on the import of basic raw materials, viz., Bulk <u>Drugs</u> that are used to produce medicines. In some specific bulk drugs the import dependence is 80 to 100%.

The government has plans to put in place a production-linked incentive (PLI) scheme to boost domestic manufacturing of critical key starting materials (KSMs) or drug intermediates, used to make bulk drugs, as well as <u>APIs</u>. That PLI could cost \$911.5 million over the next eight years.





India imports 53 APIs and KSMs from China. According to the Trade Promotion Council of India (TCPI), India imports 70% of its <u>API</u> requirements from China, mostly antibiotics and vitamins. In 2018-19, Indian <u>pharma</u> companies imported bulk drugs and intermediates worth \$2.4 billion from China.

The Indian <u>pharmaceutical</u> market should grow from nearly \$34.3 billion in 2020 to more than \$45 billion by 2025 million.





Quantum of Incentive

The fermentation based eligible, incentive for first four years (2022-2023 to 2025-2026) would be 20%, for fifth year (2026-27) incentive would be 15% and the sixth year (2027-2028) incentive would be 5%; on incremental sale of KSMs/Drug Intermediates/APIs.

For <u>chemically</u> synthesis eligible products, incentive for five years (2021-2022 to 2025-2026) would be 10% on incremental sales of KSMs/Drug Intermediates/APIs.

Related Videos: - https://bit.ly/2XVNXsY





Major Queries/Questions Answered in the Report?

- 1. What is Active Pharmaceutical Ingredient (API) Manufacturing industry?
- 2. How has the Active Pharmaceutical Ingredient (API) Manufacturing industry performed so far and how will it perform in the coming years?
- 3. What is the Project Feasibility of Active Pharmaceutical Ingredient (API) Manufacturing Plant?
- 4. What are the requirements of Working Capital for setting up Active Pharmaceutical Ingredient (API) Manufacturing plant?



- 5. What is the structure of the Active Pharmaceutical Ingredient (API) Manufacturing Business and who are the key/major players?
- 6. What is the total project cost for setting up Active Pharmaceutical Ingredient (API) Manufacturing Business?
- 7. What are the operating costs for setting up Active Pharmaceutical Ingredient (API) Manufacturing plant?
- 8. What are the machinery and equipment requirements for setting up Active Pharmaceutical Ingredient (API) Manufacturing plant?



- 9. Who are the Suppliers and Manufacturers of Plant & Machinery for setting up Active Pharmaceutical Ingredient (API) Manufacturing plant?
- 10. What are the requirements of raw material for setting up Active Pharmaceutical Ingredient (API) Manufacturing plant?
- 11. Who are the Suppliers and Manufacturers of Raw materials for setting up Active Pharmaceutical Ingredient (API) Manufacturing Business?
- 12. What is the Manufacturing Process of Active Pharmaceutical Ingredient (API)?



- 13. What is the total size of land required for setting up Active Pharmaceutical Ingredient (API) Manufacturing plant?
- 14. What will be the income and expenditures for Active Pharmaceutical Ingredient (API) Manufacturing Business?
- 15. What are the Projected Balance Sheets of Active Pharmaceutical Ingredient (API) Manufacturing plant?
- 16. What are the requirement of utilities and overheads for setting up Active Pharmaceutical Ingredient (API) Manufacturing plant?
- 17. What is the Built up Area Requirement and cost for setting up Active Pharmaceutical Ingredient (API) Manufacturing Business?



- 18. What are the Personnel (Manpower) Requirements for setting up Active Pharmaceutical Ingredient (API) Manufacturing Business?
- 19. What are Statistics of Import & Export for Active Pharmaceutical Ingredient (API)?
- 20. What is the time required to break-even of Active Pharmaceutical Ingredient (API) Manufacturing Business?
- 21. What is the Break-Even Analysis of Active Pharmaceutical Ingredient (API) Manufacturing plant?
- 22. What are the Project financials of Active Pharmaceutical Ingredient (API) Manufacturing Business?



- 23. What are the Profitability Ratios of Active Pharmaceutical Ingredient (API) Manufacturing Project?
- 24. What is the Sensitivity Analysis-Price/Volume of Active Pharmaceutical Ingredient (API) Manufacturing plant?
- 25. What are the Projected Pay-Back Period and IRR of Active Pharmaceutical Ingredient (API) Manufacturing plant?
- 26. What is the Process Flow Sheet Diagram of Active Pharmaceutical Ingredient (API) Manufacturing project?



- 27. What are the Market Opportunities for setting up Active Pharmaceutical Ingredient (API) Manufacturing plant?
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- 29. What is the Plant Layout for setting up Active Pharmaceutical Ingredient (API) Manufacturing Business?



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- Uses & Applications
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- Miscellaneous Items and Accessories
- ➤ Instruments, Laboratory Equipments and Accessories
- > Electrification, Electric Load and Water
- Maintenance, Suppliers/Manufacturers of Plant and Machineries
- Process of Manufacture
- Flow Sheet Diagram
- List of Raw Materials
- Availability of Raw Materials
- ➤ Requirement of Staff & Labour
- Skilled & Unskilled Labour
- Requirement of Land Area
- Built up Area
- Plant Layout.



- > Along with financial details as under:
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- Production Schedule
- Land & Building
- Factory Land & Building
- ➤ Site Development Expenses
- Plant & Machinery
- Indigenous Machineries
- Other Machineries (Miscellaneous, Laboratory etc.)
- Other Fixed Assets
- > Furniture & Fixtures
- Pre-operative and Preliminary Expenses
- Technical Knowhow
- Provision of Contingencies



Working Capital Requirement Per Month

- Raw Material
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- ➤ Lab & ETP Chemical Cost
- Consumable Store

Overheads Required Per Month And Per Annum

- Utilities & Overheads (Power, Water and Fuel Expenses etc.)
- Royalty and Other Charges
- Selling and Distribution Expenses
- Salary and Wages
- Turnover Per Annum
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- Equity Capital
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Annexure 2 Profitability and Net Cash Accruals

- Revenue/Income/Realisation
- Expenses/Cost of Products/Services/Items



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Reasons for Buying our Report:

- This report helps you to identify a profitable project for investing or diversifying into by throwing light to crucial areas like industry size, market potential of the product and reasons for investing in the product
- This report provides vital information on the product like it's characteristics and segmentation
- This report helps you market and place the product correctly by identifying the target customer group of the product



- This report helps you understand the viability of the project by disclosing details like machinery required, project costs and snapshot of other project financials
- The report provides a glimpse of government regulations applicable on the industry
- The report provides forecasts of key parameters which helps to anticipate the industry performance and make sound business decisions



Our Approach:

- Our research reports broadly cover Indian markets, present analysis, outlook and forecast for a period of five years.
- The market forecasts are developed on the basis of secondary research and are cross-validated through interactions with the industry players
- We use reliable sources of information and databases. And information from such sources is processed by us and included in the report



Scope of the Report

The report titled "Market Survey cum Detailed Techno Economic Feasibility Report on Active Pharmaceutical Ingredient (API)." provides an insight into Active Pharmaceutical Ingredient (API) market in India with focus on uses and applications, Manufacturing Process, Process Sheets, Plant Layout and Project Financials of Active Pharmaceutical Ingredient (API) project. The report assesses the market sizing and growth of the Indian Active Pharmaceutical Ingredient (API) Industry. While expanding a current business or while venturing into new business, entrepreneurs are often faced with the dilemma of zeroing in on a suitable product/line. And before diversifying/venturing into any product, they wish to study the following aspects of the identified product:



- Good Present/Future Demand
- Export-Import Market Potential
- Raw Material & Manpower Availability
- Project Costs and Payback Period

We at NPCS, through our reliable expertise in the project consultancy and market research field, have demystified the situation by putting forward the emerging business opportunity in the Active Pharmaceutical Ingredient (API) sector in India along with its business prospects. Through this report we have identified Active Pharmaceutical Ingredient (API) project as a lucrative investment avenue.



Tags

#Levofloxacin #Sulfadiazine #Ciprofloxacin #Ofloxacin #Norfloxacin #Telmisartan #Valsartan #Olmesartan #Artesunate #Losartan #Oxcarbazepine #Atorvastatin #Acyclovir #Lopinavir #Ritonavir #Carbamazepine #Levodopa #Carbidopa #Levetiracetam #Aspirin Sodium #Tinidazole #Ornidazole #Diclofenac #businessopportunity #projectreport #DetailedProjectReport #businessconsultant #businessfeasibilityreport #BusinessPlan #startyourbusiness #investmentopportunity #growyourbusiness #startups #business #covidbusiness #covidsmallbusiness #covid19 #APIBusiness #ActivePharmaceuticalIngredient



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NPCS is manned by engineers, planners, specialists, financial experts, economic analysts and design specialists with extensive experience in the related industries.

Our Market Survey cum Detailed Techno Economic Feasibility Report provides an insight of market in India. The report assesses the market sizing and growth of the Industry. While expanding a current business or while venturing into new business, entrepreneurs are often faced with the dilemma of zeroing in on a suitable product/line.



And before diversifying/venturing into any product, they wish to study the following aspects of the identified product:

- Good Present/Future Demand
- Export-Import Market Potential
- Raw Material & Manpower Availability
- Project Costs and Payback Period

The detailed project report covers all aspect of business, from analyzing the market, confirming availability of various necessities such as Manufacturing Plant, Detailed Project Report, Profile, Business Plan, Industry Trends, Market Research, Survey, Manufacturing Process, Machinery, Raw Materials, Feasibility Study, Investment Opportunities, Cost and Revenue, Plant Economics, Production Schedule,



Working Capital Requirement, uses and applications, Plant Layout, Project Financials, Process Flow Sheet, Cost of Project, Projected Balance Sheets, Profitability Ratios, Break Even Analysis. The DPR (Detailed Project Report) is formulated by highly accomplished and experienced consultants and the market research and analysis are supported by a panel of experts and digitalized data bank.

We at NPCS, through our reliable expertise in the project consultancy and market research field, have demystified the situation by putting forward the emerging business opportunity in India along with its business prospects.....Read more



Contact us

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- One of the leading reliable names in industrial world for providing the most comprehensive technical consulting services
- We adopt a systematic approach to provide the strong fundamental support needed for the effective delivery of services to our Clients' in India & abroad



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We bring deep, functional expertise, but are known for our holistic perspective: we capture value across boundaries and between the silos of any organization. We have proven a multiplier effect from optimizing the sum of the parts, not just the individual pieces. We actively encourage a culture of innovation, which facilitates the development of new technologies and ensures a high quality product.



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- Project Identification
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- Market Research Reports
- Business Plan
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- Industry Trend
- Databases on CD-ROM
- Laboratory Testing Services
- Turnkey Project Consultancy/Solutions
- Entrepreneur India (An Industrial Monthly Journal)

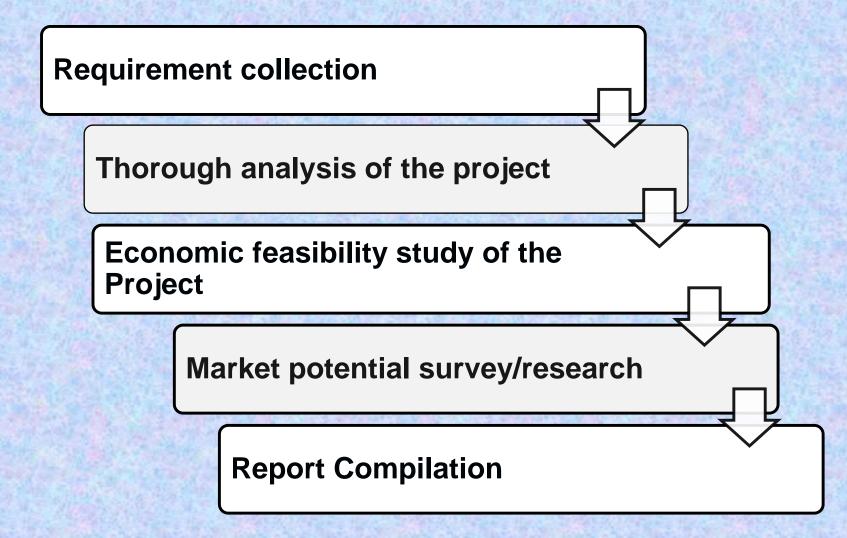


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- We empower our customers with the prerequisite know-how to take sound business decisions
- We help catalyze business growth by providing distinctive and profound market analysis
- We serve a wide array of customers, from individual entrepreneurs to Corporations and Foreign Investors
- We use authentic & reliable sources to ensure business precision



Our Approach





Contact us

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