

UPSC 2021 Preparation

Bulk Drug Park - APIs, KSM & DIs

The Central government has announced the establishment of three bulk drug parks in the country to promote the growth of domestic pharmaceutical industries. Learn about what are bulk drugs, and the benefits of establishing bulk drug parks in the country. This information will be helpful for the [IAS Exam](#) preparation.

What is a Bulk Drug?

Active Pharmaceutical Ingredients (APIs) are called bulk drugs. These are the main ingredients of a drug or medicine. The bulk drug is the key source to provide therapeutic effects or intended pharmacological activity.

The [World Health Organization \(WHO\)](#) defines bulk drug or APIs as, “Any substance or combination of substances used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.”

Types of Active Pharmaceutical Ingredients/ Bulk Drugs:

1. Chemical Synthetic Drugs
 1. Inorganic – Examples – Aluminum hydroxide and Magnesium trisilicate
 2. Organic – Examples – Aspirin, Chloramphenicol, Caffeine, etc.
2. Natural Chemical Drugs
 1. Biochemical – Examples – Antibiotics
 2. Phytochemical – Examples – Paclitaxel (taxol), Resveratrol

A bulk drug is mixed with other binding agents or solvents to prepare the finished pharmaceutical product (capsule, syrup, or tablet.)

What is Bulk Drug Park?

It is a space with common infrastructure facilities for the exclusive manufacture of APIs or DIs or KSM.

Bulk Drug Park will also have a common waste management system.

Criteria of a Bulk Drug Park Selection:

1. A land area to be not less than 1000 acres for all states except 7000 acres for hill states.
2. A state will propose only one site along with its estimated cost, feasibility studies, environmental risk assessment etc.
3. Department of Pharmaceuticals-led Project Management Agency (PMA) will assess the state proposals and will forward it to Scheme Steering Committees for approval.

Bulk Drugs – What are KSM and DIs?

Key Starting Material (KSM)	Drug Intermediaries (DIs)
It is the basic raw material that undergoes various reactions involving chemicals and solvents to form an API.	These are the chemical compounds which are formed in the intermediate stages of reaction between KSM and other chemicals and solvents.

Reason Behind Indian Government Scheme to Promote Bulk Drug Parks

1. Despite the Indian Pharmaceutical Industry is the 3rd largest pharmaceutical industry in the world (by volume); it is significantly dependent on the imports of bulk drugs or APIs. According to data mentioned by the Ministry of Chemicals and Fertilizers, in 2018-19, bulk drugs import accounted for 63 percent of total pharmaceutical imports in the country.
2. Due to the novel coronavirus pandemic and subsequent lockdowns, Indian pharmaceutical industries faced challenges as the imports of APIs were impacted.
3. In the account of the challenges posed by the interruptions in the bulk drugs supply, the government of India brought a scheme called, 'Bulk Drugs Park,' in March 2020.

Important Facts about the Scheme to Promote Bulk Drugs for UPSC	
Type of Scheme	Central Sector Scheme
Total Financial Outlay	Rs. 3000 crores
Number of Bulk Drug Parks under the Scheme	Three
Maximum grant-in-aid provided to one bulk drug park	Rs. 1000 crores
Tenure of the Scheme	2020-2025
Share of Grant-in-aid	<ul style="list-style-type: none"> • 70% of the project cost for the rest of the country except; • 90% of the project cost for the North Eastern States and Hill States (i.e Himachal Pradesh, Uttarakhand, UT of Jammu & Kashmir and UT of Ladakh)
Salient Features	<ul style="list-style-type: none"> • State Implementing Agencies (SIAs) will implement the scheme. • Bulk Drug Parks will not have formulation units inside it.

Read about important [government schemes](#) useful for competitive examinations including the IAS Exam in the linked article.

How will the Promotion of Bulk Drugs Park help Indian Pharmaceutical Industry?

1. The drug manufacturers will get easy access to world-class **common infrastructure facilities (CIF.)**
2. The facilities provided under this scheme intends to **bring down the manufacturing cost** of the bulk drugs.
3. It will promote **self-reliance in pharmaceutical manufacturing** and can be linked with India's ambition for [AtmaNirbhar Bharat](#).
4. The bulk drugs parks will also **increase the competitiveness of the bulk drug industry** in India.

Brief Overview of the Indian Pharmaceutical Industry

1. It is 3rd largest by volume.
2. It is 14th largest in terms of value.
3. India accounts for 60 percent of global vaccine production, contributing 40 to 70 percent of the WHO demand for [Diphtheria, Tetanus and Pertussis \(DPT\)](#) and Bacillus Calmette–Guérin (BCG) vaccines, and 90 percent of the WHO demand the measles vaccine.
4. The positive health outcomes out of growth in the Indian pharma industry are:
 - 36% lower Disability-Adjusted Life Year (DALY)/per person.
 - 100% eradication of Polio.
5. The positive economic outcomes out of growth in the Indian pharma industry are:
 - Around 2.7 million jobs are created directly or indirectly.
 - It has an annual trade surplus of around 11 billion US Dollars.
 - FDI inflows in the pharma industry account for around 2 billion US Dollars between 2016-2019.

The given notes can be useful for UPSC Mains GS 3 (Science & Technology) preparation along with GS 2 (Government's schemes and initiatives.) For more on [UPSC 2021](#) preparation, check the linked article.

Related Articles:

Science and Technology Notes for UPSC	UPSC Mains GS 3 Strategy
UPSC Mains GS 2 Strategy	UPSC Syllabus
Current Affairs	Daily News Analysis of The Hindu Newspaper
Static GK	NCERT Notes for UPSC