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Ingredients

SOUTH ASIA

A Saffron Media Publication

Vol. 15, Issue 10, Pages-40

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Overview of excipients in current market development

DR SANJAY AGRAWAL

EXCIPIENT'S role in designing the different dosage forms does not require any introduction. These are additive and need to be added in the formulation and the pharmacologically active substances. The main motive of adding these will increase the formulation's bulk and imparting properties. Excipients need to be standardised and validated.

There are different dosages of the excipients used in various forms like solid, liquid, and semi-solid dosage forms. While considering the ongoing development in the field of pharmaceutical advancement, formulations cover excipients that are used in the nano formulations as well. There are multi-mineral excipients co-processed excipients that need to be known by all.

Pharmaceutical excipients used in capsules and tablets

The pharma industry is ever thirsty to satisfy the therapeutic needs of the patients apart from the active ingredients. The inactive excipients play a crucial role in the formulation development process. The finished pharmaceutical produces dosage forms other than the pharmacologically active drugs or prodrugs included in the manufacturing process.

In transporting the active drug to the body where the intended drug is exerted into actions, excipients play a significant role in this manufacturing process. They may also be essential for keeping the drug from being released too early in the assimilation procedure in the varied places where it can damage the tender tissue and create gastric irritation or even stomach upset.

Some excipients are used to make the product taste and look better. It improves patient

compliance, mainly in children. Additionally, it is an inactive form of a therapeutic sense. The pharmaceutical excipients are a more critical and essential component than the modern drug product. The drug's active ingredients and other important features include diluents and fillers, disintegrants, lubricants, colouring agents, and even preservatives. Often the diluents or fillers are inert ingredients that significantly affect the physical and chemical properties of the tablet, thus affecting the biopharmaceutical profiles.

The glidants improve the powder into the tableting machines for compaction, and they tend to minimise the tendencies of the granulation to separate or segregate due to excessive vibration. The high-speed tablet machine often requires a smooth flow of the materials to die cavities or tablet molds. The uniformity of the tablet weights directly depends on how uniformly the die cavity is filled.

Surge by 30% to 50% in the prices of excipients

As per the market research, the Indian excipients industry is experiencing less than 1% of the market share in the \$7 billion global excipients industry. The alarming increase in the prices is nearly 30% to 50%, negatively impacting the pharma industry. Most excipients like lactose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, and microcrystalline cellulose are imported from the Chinese market.

Phthalates are the solvents like Acetic anhydride used as a raw material to input in the prices that have exceptionally grown up to 100%. There are freight rates which have also gone up and led to significant changes in the excipient prices. Most of the basic excipients are not manufactured in India. Today, there are only 10 manufacturers who have urged the government for timely policy interventions

towards resolving the issue.

The pharma excipients are naturally or synthetically formulated to serve multiple purposes in drugs and medicines. It is used in bulk and enhances the solubility of the medications or ingredients for the therapeutic effect of the drugs. Excipients have improved the API stability that protects from degradation. As per the records, there is no effective regulation for the excipients in India apart from the monographs.

Due to low labour costs and increased outsourcing of inorganic and organic chemical manufacture, Asia-Pacific is the fastest expanding pharmaceutical excipients market. Emerging countries such as China and India are essential players.

Global demand for excipients to exhibit steady growth

According to a new analysis, the global market for pharmaceutical excipients is expected to increase at a mid-single-digit CAGR to reach \$7.7 billion by 2022. Due to increased demand for pharmaceutical and biologic products and a significant number of excipient manufacturers in this region, North America has the highest share of the pharmaceutical excipient market. Europe is the second most populous continent, followed by Asia-Pacific and the rest of the world.

Due to low labour costs, increased outsourcing of inorganic and organic chemical manufacture, and rising governmental spending on health care, Asia-Pacific is the fastest expanding region for pharmaceutical excipients. Emerging countries such as China and India are essential contributors. India produces 50% of these substances, which are made alongside active compounds by firms, and China and Europe are responsible for the remaining 50%. In terms of intermediates, 80 per cent of them are imported, the most of them are from China. This demonstrates the extent to which this dragon country is reliant on it.

Like active pharma ingredients, excipients play an essential role in pharmaceutical formulations (API). Excipients serve as inert ingredients that act as carriers for drug components in any formulation and facilitate the sophistication of dosage forms for specialised purposes such as controlled release/sustained release dosage forms with precisely controlled physicochemical characteristics.

Excipients are now incorporated in solid formulations for long-term stability and bulking. These are diluents or fillers used to improve



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Shutdown of units caused price rise

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Impact on Price

- When it comes to pharmaceutical products, the global pharmaceutical sector has been hit hard by the recent outbreak of Coronavirus disease (Covid-19). Coronavirus illness is becoming more prevalent over the world, and there is a growing demand for efficient treatment alternatives.
- According to Pharmexcil statistics, the cost of Penicillin APIs increased from \$6.16 per unit in January 2020 to \$8.69 per unit in October 2020.
- Moreover, the APIs producer found that prices for antibiotics such as Amikacin, Doxycycline, Azithromycin, Dexamethasone Sodium, and Ornidazole have increased by 13 to 18 per cent, as India imports them mostly from China.
- Anti-asthmatic medicine Montelukast sodium costs \$705.93- 787.38 per Kg in October 2020, compared to \$447.99- 515.87 per kg recently.
- The prices of vitamins and penicillin have also attained a lucrative growth due to sudden rise in their prices by 40 to 50 per cent as that of the original existing prices.
- For example, Heparin (an anticoagulant) is in high demand to reduce the risk of

Covid-19 infection in patients suffering from heart attacks, strokes, and lung or pulmonary embolism.

- During the Covid-19 pandemic, the price of azithromycin, paracetamol, and nimesulide APIs increased by 60 to

The latest death toll
much exceeds SARS or
MERS pandemics

190 percent. Shutdown of Chinese API production units caused price rise. During the Covid-19 epidemic, the demand for APIs increased, causing a shortage. These shortages drive up API prices. This signifies that price of APIs hiked due to continuous coronavirus outbreak.

Impact on Demand

The demand for effective treatment is enormous. Due to these positive features, APIs are required for drug manufacture,

indicating a high future demand for APIs.

Recognising existing or predicted future increases in customer demand, healthcare organisations and government agencies call on industry to enhance API production.

Government also takes many steps to address the need for medicine production.

Outlook

The latest death toll much exceeds SARS or MERS pandemics and has rapidly moved outside of mainland China. At this time, the virus has spread to 177 nations, and China expects a second wave of infection from imported cases. The situation is still fluid, and the outbreaks present and potential interruptions are expected to damage pharmaceutical supply chain manufacturing and distribution operations.

This outbreak may be a wake-up call for the pharma sector and Governments. A single market for crucial ingredients and manufacturing activities reveals long-standing vulnerabilities of pharmaceutical businesses. ◯

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Assessing a substance's eligibility

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therapeutic compliance. The excipients help to keep APIs stable and protect them from deterioration, and it also guarantees a stable and repeatable physical product. Diluents, such as lactose and microcrystalline cellulose, are among the excipients. Disintegrants such as sodium starch glycolate and croscarmellose sodium are also used. PVP and HPMC are used as binders. Magnesium stearate is used as a lubricant, and colloidal silicon dioxide is used as a glidant.

The use of 'inert substances' as drug transporters can be traced back to the invention of medicine. Compounding rudimentary medications and formulating lotions and ointments was done by the ancient Egyptians and Greeks, and the father of formulation was Hippocrates. Galen is widely regarded as the father of science (c.130- c.200 AD). Excipients have traditionally been defined as inert compounds employed as diluents or vehicles in drug formulations, i.e., non-active ingredients in a formed drug product.

According to the IPEC (International Pharmaceutical Excipients Council), An excipient is any material other than functional medicine. Excipients are natural or synthetic substances

formulated alongside active ingredients in pharmaceutical formulations for long-term stabilisation, bulking up solid formulations containing potent active ingredients (often referred to as 'bulking agents,' 'fillers,' or 'diluents,') or conferring a therapeutic enhancement on the active ingredient in the final dosage form of pharmaceutical formulations. These could help with drug absorption, reduce viscosity, or improve solubility.

Excipients can also aid in the manufacturing process by improving powder flow or non-stick qualities, preventing denaturation of aggregation throughout the desired shelf life, and enhancing stability.

Excipients make up the majority of any medicinal product, and their proportion in any pharmaceutical preparation surpasses two to three times that of the API. As a result, factors such as functionality, regulatory status, sources, cost, consistency, bioavailability, physicochemical properties, stability, and pharmacokinetic parameters, among others, play a significant part in assessing a substance's eligibility as an excipient.

A pharmaceutical excipient is a natural or synthetically manufactured material that serves numerous pharmaceuticals and medications. It's employed as a bulking or stabi-

lising agent, as an agent to improve a drug's solubility, or as a component to improve its therapeutic impact.

Some excipients may also add extra value to a drug or treatment during the production or handling. Excipients are also used in applications where drug integrity and stability in vitro must be maintained. The type and amount of excipient used in a pharmaceutical formulation are determined by whether the drug will be taken orally or given intravenously. Because certain excipients can cause an undesired chemical reaction when used with an active substance or in a specific environment, careful excipient selection is required.

Although, excipients are utilised in the chemical food and beverage industries, they are strictly regulated in the pharmaceutical industry. This puts a lot of strain on pharmaceutical excipients makers, who have to follow many process-related and regulatory procedures to get their goods to market. Aside from this, a slow but persistent drop in expenditure in pharmaceutical research activities could stifle the worldwide pharmaceutical excipients market's expansion. ◯

(The author is a leading pharmaceutical consultant)