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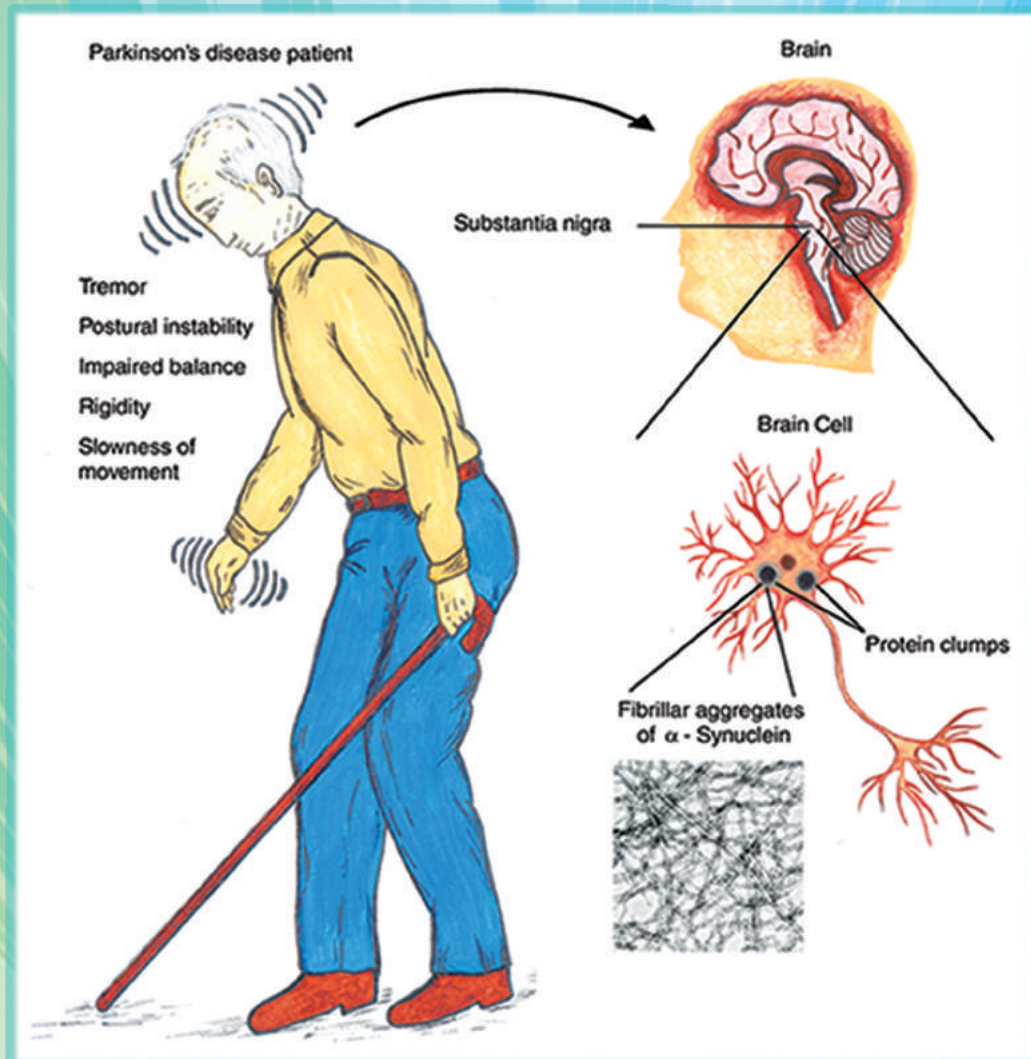
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Current Efficacious Management of Parkinsonism

Page No: 19



Innovation in API - Indian Market 2020

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Introduction

API – (Active Pharmaceutical ingredient) is the part of any drug that is biologically active and produces intended effects. India plays an important role in the global Pharmaceutical sector. API market value is expected to grow US\$247 billion by 2024. The global demand of higher quality and low cost of API is increasing day by day. API is the largest segment of Pharmaceutical market. The global API market is classified in three categories such as synthetic API, Biotech API and HPAPI.

Current Status

China is the largest supplier of API worldwide. Due to COVID-19 emergencies API production has been hampered in China which had created lots of problem in supply chain. It is believed API market scenario will change after the emergency of Novel Coronavirus. Mainly the Indian active pharmaceutical ingredients market manufacturing segments is dependent on two sectors 1) branded and 2) generic or unbranded. India exports 30% to North America, 16% to Europe and 17% to Africa.

Currently, Less than 2000 APIs companies in China and India are leading the world. Top manufacturer of Active Pharmaceutical Ingredients in India are Sun Pharma, TAPI Pharmaceuticals, GSK, Aurobindo Pharma are leading as a top class supplier in the world.

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Rise of API Market in India

COVID-19 Crisis

According to Pharmaceutical expert India should create an ecosystem for manufacturing of our own API. Even they have identified APIs that India would like manufacturer to focus on. After this crisis India would be the most reliable substitute. According to sources "The Indian government has set aside 1.2 billion dollars for pharma industries to shift country away from China." There are several claims that due to this crisis China is not being able to maintain its position as the world's largest manufacturing hub. The COVID 19 outbreak has already created major problem in supply chain. As per global data India has the largest number of CMOs and all of them have manufacturing facilities with the approval of US FDA.

Expiry of Patent

The patent expiry of many blockbuster drugs that is an ongoing process and is believed to be one of the major causes to further contribute to the growth of the active pharmaceutical ingredient market in India. Due to patent expiration the drug molecule would categorise in generic form, increasing the number of small molecules in clinical trials and increasing outsourcing by pharmaceutical industries. Many of Pharmaceutical companies are looking for generic drugs due to patent expiration. The increase of the biotechnology sector in India has caused an increase in biotech API market as well, but still this market continues to lag behind the synthetic API market.

Need for Complex Molecules:

The most important trend today we see in the global API market is increase focusing on complex formulations in generics as a part of development. This is mainly because of patient populations, all those with chronic diseases and those requiring the treatments in oncology, immunotherapy, and respiratory etc. These are supposed to be one of the very complex conditions that are demanding a wide range of complex treatments using complex molecules.

Generic Focus

The drugs that are mainly in the pipeline for the APIs are the ones whose patent is off patent or soon-to-be off patent.

Quality Concerns

As per report the API manufacturer in China does not follow the proper guidelines provided by FDA. This has been observed that relabeled API did not feature the name or address of original manufacturer on Certificate of Analysis. The recent issue with tainted valsartan that was produced in China is a case in point. Somehow due to these incidents China has been losing trust among international customers when it comes to API. In addition to this due to COVID outbreak international customer are looking for substitute API manufacturer.

Future Trends

After COVID-19 outbreak, Indian government is working on increasing the API production in house result of which, India will become the hub of API for the world. Indian pharmaceutical industry ranks one among the top

API markets in the world and China being its major competitor. The lower cost of the manpower and the growing technology and innovation are some of the main factors supporting its growth. The ongoing patent expiration is providing a great opportunity to boost the revenues of API market in India. Unlike China, India follows strict guidelines for drug manufacturing due to which Indian API gained trust worldwide. Indian API market holds huge capacity not only for domestic market but also has capability to export. As per report India API market will grow at CAGR 10.67 percent in the next three years. The Indian companies manufacturing API are being obliged to the

standards and are compliant with many international regulations. Also the improvements in the field of technology in the country have enabled many manufacturers to venture into the highly regulated markets of the countries like United States and Europe. In fact, India has been recognized as one of the leading global players with the filing of large number of DMFs and dossier registrations for active pharmaceutical ingredients, with several manufacturing facilities approved by the regulatory authorities of developed countries.

Conclusions

In coming years China will not be able to hold their position as a leader in APIs market. Indian

government has started looking into the expansion of API market post COVID outbreak. India will be the hub of APIs supply for the global market in future. Government's new policy, improving IP system & manufacturing process available natural resources, cheap manpower, advanced technology, support of several countries round the globe is creating a new healthy ecosystem for set up manufacturing of APIs in India. Few big manufactures likes Sun Parma, TAPI might be the front runners along with several small and new manufacturers. Government of India's Pharma Vision 2020 aims to make India a global leader in pharmaceutical segment.



Neuroscience is an introspective science. Human brain studies itself using its own substrates – ions, chemicals and currents. The deeper the studies, more and more unanswered questions arise, with the vague awareness that the Self is beyond brain's comprehension. The quest towards self realization, which is an experience rather than mere knowledge begins at these frontiers of neuroscience.



**RANDOM
THOUGHTS**

Puerarin is the major bioactive constituent isolated from the root of the *Pueraria lobata* (Willd.) Ohwi, known as Gegen (Chinese) in traditional Chinese medicine. Puerarin has a wide spectrum of pharmacological properties such as cardioprotection, vasodilation, neuroprotection, antioxidant, antiinflammation, anticancer, alleviating pain, promoting bone formation, attenuating insulin resistance, and inhibiting alcohol intake. However, due to the polyphenol ring and polyhydroxy groups in puerarin structure its water and fat solubility is low. It is also insoluble in chloroform, difficult to be absorbed through the gastrointestinal tract, has low oral bioavailability, which limits the clinical application of puerarin. At present, there is only one dosage form, the puerarin injection is in clinic. After oral administration in adults, 0.78% of puerarin is excreted in urine after 36h, and 73.3% is excreted in feces after 72 h. This revealed that puerarin is not highly absorbed after oral administration because of its poor solubility. To improve the bioavailability of puerarin, an inclusion complex of puerarin- β -cyclodextrin (β -CD) is a good alternative.

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