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Updates on natural extracts in pharma

DR SANJAY AGARWAL

FOR several thousand years, medications have been based on plants, and they may be closely tied in time and skill to the origins of wine-producing, which date back over 9000 years in Georgia and not much later in Armenia. Plant-based medications have also been used to treat Traditional Chinese Medicine (TCM) patients for thousands of years. More importantly, there has been a recent resurgence in using these natural medications.

In comparison, only recent advancements, roughly over the previous century, have impacted synthetic chemistry in "pharmaceuticals," which grew significantly. The second wave emerged in the 1980s from the emerging field of biopharmaceuticals, which, like synthetics, has been vigorously assaulted in recent decades by so-called generics/biosimilars. However, it should be remembered that natural products have frequently aided the development of new therapies and treatments in both sectors, such as Taxol, a cancer therapy made from yew needles.

Natural products are widely regarded as sustainable, biodegradable, green, kosher, and halal in various industries, including pharmaceuticals, nutraceuticals, nutrition additives, cosmetics, flavours, and crop protection agents. Manufacturers of natural extracts face obstacles in keeping their products in worldwide markets and establishing new ones, as regulatory requirements and sales pricing change from country to country.

One key aspect that rarely comes up in discussions of synthetics vs. herbal raw-based product molecules in healthcare applications is the fact that herbal raw-based products, whether in the form of a single compound or a complex mixture (i.e., extract), are biodegradable by design, or perhaps better, by origin. This is more than can be claimed for most biosynthetic medicines and chemosynthetic substances. Manufacture of the latest synthetics, i.e., the so-called "high potency pharmaceuticals," can only be handled under the strictest safety conditions; those participating in production must operate under rigorous protection. It is self-evident that the handling, particularly the disposal, is critical.

Natural treatments, such as herbal extracts and natural chemicals, are a valuable source of nutraceutical and pharmaceutical ingredients. They are essential in the prevention, treatment, and maintenance of health and the prevention and treatment of various maladies or chronic and acute disorders, such as metabolic, inflammatory, neurological, and immune system issues. As a result, interest in natural goods or natural product medication discovery has grown and continues to grow worldwide in the previous decade. This might be attributed to minor side effects compared to traditional treatments, which

are sometimes inefficient in treating disease, particularly chronic issues.

This aspect aims to bring together intriguing material for scientists who work with natural goods, with a focus on nutraceuticals and pharmaceuticals. The emphasis will be on research and reviews on new formulation design and characterisation, natural product stability, pharmacokinetic and pharmacodynamic characteristics, and pharmacological inquiry. Other parts of technology, nutraceuticals, or pharmaceuticals will also be welcomed.

Herbal Product Regulation

Herbal medicinal goods are carefully regulated in Europe. Monographs detail every herbal raw or raw portion used in the manufacture of herbal goods. They are based on the European Medicines Agency's Committee on Herbal Medicinal Products (HMPC). The efficacy, therapeutic indications, toxicological safety, and extract definition are all covered in these works. The European Pharmacopoeia establishes different standards for the quality of herbal products.

It is uncommon for new products incorporating herbal raws to be developed that have not



previously been described by HMPC. The costs of (pre-)clinical trials are high, making product development unaffordable. Furthermore, the market application process is time-consuming and risky, deterring potential investors.

The international strategy is not uniform. According to their "Botanicals" regulation, the US-American Food and Drug Administration has highly stringent requirements for phytomedicine licensing. Herbal products are generally classified as dietary supplements rather than standard medications. According to the FDA, these "supplements are not designed to treat, diagnose, prevent, or cure diseases," according to the FDA.

Towards a deeper understanding of the active ingredients and modes of efficacy actions not only allows but also requires the use of innovative manufacturing techniques, as well as actual process development and manufacturing data evaluation methods like QbD (Quality by Design) combined with PAT (Process Analytical Technology) approaches for regulatory approval. In the meantime, at the institute in

Clausthal's Sustainable Manufacturing Center for the Chemical-Pharmaceutical Industry, such technologies are being transferred from biologics to botanicals, effectively applied, and made suitable for industrialisation.



Aside from pharmaceuticals, there are a few more essential elements of herb-based goods for other branches:

Dietary supplements based on herbs

- Production size 10–100 times that of pharma,
- Controlled environment, but more freedom in the extraction process,
- Semi-purified goods

Crop protection and pesticides based on herbs

- Multiply by 100–1000, in comparison to pharma, a more extensive scale of production
- A regulated environment in terms of quality but more latitude in terms of the extraction process
- Goods that have been partially purified

Herbal raw material and resource cultivation

- **Pharma:** Herbal raw material must be acquired from natural habitats, which can be difficult due to higher natural variability, environmental effect, and supply chain management risks, among other factors.
- Herbicides, nutritional supplements, and crop protection: Because of the advantages in terms of quality, logistics, and security, cultivated herbal raw material is selected.

In herbal pharmaceutical manufacture, quality assurance is based on intense and expensive laboratory work with a lesser degree of automation and data use. Inline measurements, data collecting and evaluation, and real-time analysis of herbal raw material can significantly enhance the amount of data collected and ensure consistent quality while preserving or even lowering personnel costs.

Quality control of the traditional herbs and herbal products

Human beings value quality in every element of their lives. The quality of medications eaten by people is critical since they are used to maintain human health. Strict norms and regulations govern the quality control of synthetically manufactured chemical medicines. Before they may be marketed and ingested by patients and consumers, they must go through various tests and quality control checks. Because of the strictness of the laws, the quality of synthetically created medications is kept up to par, ensuring

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Herbal raw material must be acquired from natural habitats

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the goods' safety and efficacy.

Herbal medicinal goods are derived from plant resources for human treatment and well-being. The quality of herbal medicines must be monitored similarly to chemically manufactured medicines. However, compared to synthetic pharmaceuticals, the regulatory standards for herbals are less stringent. This is causing a drop in the quality of herbal products due to intentional and unintentional adulteration, drug substitution, and various other factors that lower the rate of herbal materials marketed and ingested for healthy survival. Instead, it has dangerous consequences for customers' health. Controlling the quality standards of herbal drugs and goods is therefore critical for improving humanity.

As the demand for herbal medications grows, it is necessary to ensure their quality. Herbs are used by about 80% of the population for treatment, cure, and prevention. As a result, several methods and approaches must be implemented to check and ensure the appropriate quality of herbal materials and products. There should be rules and norms for conducting quality control tests on herbs that are almost as stringent as those for synthetic medications. This will aid in maintaining herbal pharmaceutical quality standards, which is a complex undertaking and an urgent requirement

in pharmaceutical research and quality assurance.

Preference for natural products to drive the herbal extracts market

The herbal extracts market in India has grown at a fantastic rate as people become more aware of the health benefits of using herbal products. Exports of high-quality herbal extracts to the United States, Canada, Ukraine, South Korea, the Czech Republic, Israel, France, Taiwan, Nepal, and other countries have fueled the market. The market's earnings have increased due to overseas clients' preference for Indian products due to the health advantages of various herbs. Plant or herbal extracts are natural products that have become increasingly popular. Companies in the pharmaceutical, cosmetics, and food and beverage sectors use such goods as raw materials or ingredients worldwide.

Due to the demand and supply of herbal extracts from China and India, Asia Pacific is one of the fastest expanding geographies. During FY'2017, the use of herbal extracts in India's pharmaceutical and nutraceutical industries contributed a significant portion of the overall revenues of the businesses in the field. The increased usage of plant extracts in the preparation of beauty products has stemmed from the growing desire for natural cosmetics.

Because of the food processing industry development in developing countries like India, China, and Indonesia, Asia Pacific is expected to drive market growth. The market is dominated by the top seven businesses, which control most of the market. Arjuna Natural Extracts Ltd., Synthite Industries Limited, Sami Labs Limited, Vidya Herbs Private Limited, OmniActive Health Technologies Ltd., Indfrag Limited, and K.Patel Phyto Extractions Pvt. Ltd. are among the country's major companies in the herbal extracts business.

Synthite Industries leads the India Herbal Extracts Market in terms of revenue. Plant Lipids Pvt Limited rose to second place in market revenue, thanks to its manufacturing facilities in India. By FY2022, the revenues generated by herbal extracts market participants in India are expected to increase. During FY2022, sales of herbal extracts to the pharmaceutical and nutraceutical industries are expected to lead the overall market revenues. F&B customers will contribute more to overall market sales in FY2022, as people turn away from packaged foods with high chemical content and toward dietary supplements with herbal extracts. ○

(The author is a leading pharmaceutical consultant)



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