

Evaluating the Indian pharmaceutical supply chain's adoption of green chemistry

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Abstract

This report presents the first benchmarking analysis of green chemistry (GC) adoption across the Indian pharmaceutical supply chain based on data from industry leaders driving such efforts. evaluating the use of green chemistry in the Indian pharmaceutical supply chain Abstract According to the research, Indian companies that make both generic drugs and active pharmaceutical ingredients (APIs) show a strong interest in and progress towards using GC principles. Moreover, 20% of Indian enterprises do not use any GC measurements, and the majority (65%) rely on wastewater treatment and disposal rather than source reduction. The study discovered that when it comes to applying GC principles, generic pharmaceutical businesses are more advanced than API producers. The top two factors mentioned for increasing GC implementation in India were cost savings and environmental laws, whereas regulatory risk and time constraints for medicine delivery were cited as the two biggest obstacles. The report ends with a few recommendations for broadening GC usage in India.

Introduction

The pharmaceutical supply chain in China and India presently produces the majority of the active pharmaceutical ingredients (APIs) for both generic and brand-name drugs. China provides about two thirds of the world's APIs, despite the fact that India's pharmaceutical companies have been proven to have superior capabilities in formulation research, finished medication manufacturing, and product marketing in regulated markets like the United States and Europe [1]. The Indian pharmaceutical business has experienced annual revenue growth of 12%, and it currently supplies 20% of all generic drugs worldwide, second only to China. By 2022, 92% of all pharmaceuticals will likely be generic, thanks to increased efforts to lower healthcare costs. India is well-positioned to benefit from this trend; in just the first half of 2017, Indian pharmaceutical companies received 40% of U.S. endorsements for non-exclusive medicines, up from 35%.

Simultaneously, the two India and China's drug industry has gone under investigation for the contamination coming about because of medication producing. Inadequate management of waste from pharmaceutical manufacturing has been blamed for the emergence of antibiotic-resistant bacteria, or " superbugs" [1]. From 2007 onward, Larsson et al. emphasized this issue in a study of pharmaceutical manufacturing effluents in Hyderabad, India, and demanded that environmental considerations be incorporated into ICH GMP guidelines. India recently shut down four polluting businesses in the Hyderabad area, and China has regulated nearly 40% of factories in 30 industrial provinces, raising concerns about the pharmaceutical supply chain's security. Scientists, NGOs, and strategy producers have called for activity by the worldwide drug industry to address the natural presentation of its whole Programming interface production network. The manufacturing and sales of pharmaceuticals to U.S. and EU-based businesses and healthcare systems could be disrupted if this issue is not addressed.

The authors advocate green chemistry (GC) despite the clear corrective strategy of improved waste stream management because of its emphasis on source reduction and large cost savings [2]. The word "GC" refers to "the design of chemical goods and processes that decrease or eliminate the formation of hazardous chemicals." The drug industry was among the first to embrace GC because to its tremendous potential to reduce costs and hazards. Researchers have found a

considerable decline in the Toxics Release Inventory (TRI) discharges from the pharmaceutical sector in the United States, suggesting a connection with GC use. In addition, little is known about its current adoption in China and India, as well as the obstacles, drivers, and opportunities for the future. A recent benchmarking study of the global pharmaceutical supply chain showed that generic drug companies, API manufacturers, and smaller R&D pharma companies are interested in using GC principles and have made some progress in doing so despite not disclosing this information to the public. However, because the study only included six Indian businesses, it was unable to provide comprehensive insights into this significant pharmaceutical market [3].

This paper aims to fill this void and has three primary goals:

a) evaluate the current level of GC adoption by Indian API manufacturers and pharmaceutical companies; b) investigate the factors that prevent the industry from adopting GC more widely, as well as the opportunities to do so by the Indian pharmaceutical industry and API manufacturers.

The paper's main contribution is that it is the first attempt to benchmark GC adoption by the Indian pharmaceutical supply chain using data from representatives of the industry leading such efforts [4] . The paper starts with an outline of green science and its reception by the drug business. An overview of environmental pollution, current regulations, and emerging GC initiatives are presented next, with India as the focus. The results of the study and a discussion are then presented by the authors along with the study's objectives and methods. A summary of the most important findings and suggestions for future

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research, practice, and policy are included in the paper's conclusion.

After a brand name drug's patent expires, generic drug companies make copies that are identical in API, strength, and route of administration [5]. In 2015, the global market for generic drugs was worth \$200 billion. Over the next few years, it is expected to grow at a rate of 10.8 percent, reaching \$380 billion by 2021. Due to their cost advantage and highly educated workforces, China and India have emerged as the leading markets for manufacturing API and research and development outsourcing. India's manufacturing costs are estimated to be 30-40% lower than those in Western Europe and the United States, and labor costs are one-seventh that of the United States. Additionally, it was discovered that operating an FDA-inspected manufacturing plant in India costs 50% less than in developed nations.

Conclusion

The global chemical industry, which outsources its early-stage intermediates, advanced intermediates, and finished products, has long viewed India as a manufacturing hub. Most of these early stage and advanced intermediates are produced through chemical reactions that are inherently hazardous and polluting, including sulphonation, nitration, chlorosulphonation, reduction, fusion, diazotization, and Friedel-Crafts. Large quantities of highly acidic or alkaline waste streams from these operations are extremely difficult to store, handle, and treat. Responsible waste treatment and disposal necessitate investment and add significant cost to the product. When it comes to addressing environmental issues, small and medium-sized businesses (SMEs) make up a large portion of India's manufacturing sector. As a result, they face numerous constraints, such as limited space, restricted access to new ideas and knowledge, and insufficient human and financial resources to invest in cutting-edge technologies. Rivalry from different nations providing items for extremely minimal price and persistent constrains from worldwide clients to lessen the cost of intermediates and completed items have driven Indian organizations to search for ways of diminishing gushing treatment costs and do what's absolute minimum to deal with their squanders [6-8].

Due to the hazardous waste it produces, India's Environment Ministry has classified pharmaceutical manufacturing as falling under the "red category." According to recent studies, the environmental pollution situation in India's pharmaceutical centres of Hyderabad and Visakhaptanam is getting worse. Antibiotic resistance is one of the largest hazards to human health in the twenty-first century, according to the World Health Organization, and the discharge of untreated wastewater from the manufacture of antibiotics is particularly worrisome. In a 2007 Swedish investigation, it was discovered that the effluent of a wastewater treatment plant serving 90 bulk medicine factories near Hyderabad included antibiotics like ciprofloxacin in concentrations 1,000 times greater than those that were toxic to some bacteria. The releases also resulted in daily losses of \in 100,000, according to the researchers. Recently, 25 pharmaceuticals against fungi were tested in

the direct surroundings of bulk drug manufacturers near Hyderabad. The researchers discovered that 95% of the samples contained drugresistant bacteria and that environmental specimens from all 28 different sampling sites were contaminated with antimicrobials. Seven out of every eight travelers to India brought drug-resistant bacteria back to Sweden, according to a 2010 Swedish study.

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