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From New Drugs to New NDDS (Novel Drug Delivery Systems): The Paradigm Shift

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Abstract: ***Drug discovery, which is a result of tedious efforts of scientists resulting from a perspicacious, inventive and rational strategic approach of Novel Drug Designing & Development focusing upon drug designing methodologies, biological targets, medicinal chemistry of prospective molecules, pharmacology, complete pharmacokinetics and pharmacodynamics, drug absorption and metabolism, drug delivery routes ,pharmaceutical and biomedical analysis, pharmaceutical biotechnology subsequently resulting in clinical drug evaluation. Next comes the rational approach of molecular properties, receptor based modeling, details of symptoms, pathogenesis of disease, a complex approach which often appears as a multi-dimensional puzzle .In view of the issues mentioned, the key to tackling the challenges such issues pose to both the future viability of the pharmaceutical industry and advances in healthcare is to substantially increase the number and quality of innovative, cost-effective new medicines, without incurring unsustainable R&D costs. Drug delivery is the process of administration of the drug into the biological system of the patient, for achieving the desired therapeutic effect. Hence to summarize it all the drug delivery system is extremely important to estimate the efficacy of a drug. Pharmaceutical companies must now focus on this opportunity of introducing NDDS as a means of extending the life cycle of their noteworthy discoveries and survive with flying colors in this struggle for the survival of the fittest, and for providing additional revenue generation. To provide an impetus to the critically falling status of the sustainability of the pharmaceutical industry, this shift in focus could prove to be of paramount importance.***
Keywords: NDDS, drug delivery, pharmaceutical industry, research, clinical trials.

I. INTRODUCTION

Drug discovery, which is a result of tedious efforts of scientists resulting from a perspicacious, inventive and rational strategic approach of Novel Drug Designing & Development focusing upon drug designing methodologies, biological targets, medicinal chemistry of prospective molecules, pharmacology, complete pharmacokinetics and pharmacodynamics, drug absorption and metabolism, drug delivery routes ,pharmaceutical and biomedical analysis, pharmaceutical biotechnology subsequently resulting in clinical drug evaluation. Next comes the rational approach of molecular properties, receptor based modelling, details of symptoms, pathogenesis of disease, a complex approach which often appears as a multi-dimensional puzzle. The solution of this arduous and perplexing puzzle of new drug discovery, though has been achieved successfully over the years but nevertheless it goes without saying that it is a result of extreme hard work, engaging multiple, matchless intellects with paramount capabilities in multiple fields and the most important of all time taking. At times a drug discovery, followed by completion of clinal trials, obtaining patents, FDA approvals etc. is an extremely tedious journey for the team involved. On an average in the US, it takes an average of 12 years for an experimental drug to navigate from the lab to the end consumer or the patient. That is, if it makes it. On an average only, a fortunate few in thousands of drugs entering into preclinical testing progress to human testing. Out of that again only maybe one of these drugs that are tested in people is ultimately approved. The chance for a new drug to actually, make it to market is thus maybe only 1 in thousands which isn't at all an encouraging number. Unfortunately for scientists or inventors of new drugs their entire life time is often timed out before they can see the success of their invention. This is just one facet or one face of the coin. When we consider the resources used, the number of US dollars that pharmaceutical companies spent, on average, to bring a new drug to market according to a study, health economists peg the current cost of drug development at US$1.3 billion, others at US$1.7 billion[1]. This figure obviously is quite a fortune and at the same time often out of reach for companies in the developing countries.

Quite a number of research works analyze this situation of unprecedented events, one such work [2]discusses the productivity challenges and trends faced by the pharmaceutical industry following low productivity, rising R&D costs, dissipating proprietary products and dwindling pipelines. This study also addresses underlying issues in drug failure and attempts to narrow gaps in current drug discovery processes, to boost productivity. An article on the same[3]discusses that the pharmaceutical industry is under growing pressure from a range of environmental issues, including major losses of revenue owing to patent expirations, increasingly cost-constrained healthcare systems and more demanding regulatory requirements.

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II. OBJECTIVES

In view of the issues mentioned, the key to tackling the challenges such issues pose to both the future viability of the pharmaceutical industry and advances in healthcare is to substantially increase the number and quality of innovative, cost-effective new medicines, without incurring unsustainable R&D costs. A study published in PharmacoEconomics[4] concludes that whether faster development times, quicker termination decisions or higher success rates derive from public policy initiatives, better management, or new technologies, the impact on R&D costs can be substantial. Ultimately, the increased efficiency could result in more innovation and new therapies reaching patients sooner. An article [5]discusses the changing structure of the pharmaceutical industry, it discusses the creation of a market for biomedical science and increased vertical competition within the industry are likely to spur innovation and raise productivity, but they also could induce socially wasteful spending and weaken academic science. At the same time with various factors in view, the industry faces severe patent challenges it states that the number of new compounds approved annually by the U.S. Food and Drug Administration (FDA) has fallen from an average of 35 in 1996–2001 to 20 in 2002–07 [6]. At the same time the pressures for acquiring patents or improving the patent status has grown critical as a result of the growing frequency of authorized generics with important implications for the welfare of prescription drug consumers, and their effect on revenue generation. Research on natural products with medicinal values offers a promising arena for obtaining patents as, they have been an invaluable source as therapeutic agent, but in the past not much has been achieved in this territory. A study states that recent technological advances that help to address these issues, coupled with unrealized expectations from current lead-generation strategies, have led to a renewed interest in natural products in drug discovery[7]. Significant work has been done on natural products, a study discusses the role of medicinal Natural product in the 21st century [8].

Drug delivery is the process of administration of the drug in to the biological system of the patient, for achieving the desired therapeutic effect. The method by which the drug is delivered is of paramount importance, as it has a significant effect on its efficacy. Novel drug delivery system involves various approaches like medical devices or drug-device combination products. Certain drugs formulations possess an optimum concentration range within which maximum benefit is achieved, and concentrations above or below this range can be toxic or produce no therapeutic benefit at all. Hence to summarize it all the drug delivery system is extremely important to estimate the efficacy of a drug. As mentioned earlier the development of new drug molecule is now an expensive and time taking process. Various research articles describe the issue in much details[9].Hence delivering drug at controlled rate, timed release, targeted delivery are certain appealing methods and thus have been sought after with much interest by the innovator pharmacy companies to compete the race on drug inventions. It is interesting to note that considerable work and many publications from USA, Europe are authored by Indian researchers[10-12].

Certain studies suggest that skin[13]and buccal[14]and nasal mucous membranes [15]might prove to be excellent routes of delivery for certain class of drugs. In fact, these studies have initiated a process new research for the development of novel drug delivery systems an arena not treaded much long back. This is now instituted as controlled-release technology (CRT). Some examples of CRTs are transdermal and trans mucosal, controlled-release delivery systems, nasal and buccal aerosol sprays, drug-impregnated lozenges, encapsulated cells, oral soft gels, iontophoretic devices to administer drugs through skin, and a variety of programmable, implanted drug-delivery devices. [14]. In fact the drug delivery system often determines the efficacy of the API and hence plays a major role in the success of the same for example an analgesic drug when delivered to the patient as an oral fast dissolving system might have a faster action than the conventional form. Hence such NDDS can be easily considered as different drug entities. In the recent time combination drug therapy has been accepted and considered as a favorable alternative to treat certain diseases like Diabetes, cardiovascular diseases, Cancer, HIV (AIDS), CNS or even infectious diseases. These discoveries and patents for the same has subsequently provided impetus to the growth of pharmaceutical industry [16]. Hence in the wake of this tremendous pressures faced by pharma majors as innovates go off patent, the only ray of hope to extend the benefits of their inventions is to focus on novel drug delivery systems which can obtain patents to take them through, in these critically competitive times.

III. METHODS

Hence in these competitive times when the pharmacy industry is going through this tough phase with research costs going up and shrinking budget allocations, subsequently rising pressures for patent establishing. Pharmaceutical companies must now focus on this opportunity of introducing NDDS as a means of extending the life cycle of their noteworthy discoveries and survive with flying colors in this struggle for the survival of the fittest, and for providing additional revenue generation when the new drug entity discovery has somewhat stagnated. Conventional means of drug delivery has been through tablets and capsules, orally, or injectables through the blood stream, or ointments or gels through skin, but off late new approaches for drug delivery like entrapment of drugs in small vesicles and then injected into the blood stream, have attracted much attention. Specific materials with

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exceptional biocompatibility like polymers have been used for this. These biocompatible materials can be worked upon and developed to produce exceptional results for drug administration. Patenting combination drug delivery systems and formulations has been proven to be very beneficial for the sustainment and growth of pharmaceutical industry. This process of focusing on drug delivery systems could mean breakthroughs even for pharma majors in the developing countries for whom new drug patents have always been a distant dream. Certain drugs like analgesics, anti-inflammatory, anti-infective and the like whose onset of action if fastened by minutes or hours can add a new dimension to its usage are worth taking into consideration. Drugs used in emergency medicine too could be taken into this class and newer studies be conducted to establish possibilities of newer deliver system to improve the efficacy. Studies could be conducted and are also being done on improving drug bio availabilities, reduce adverse effects, minimize drug interactions. Scientists are now working on site specific drug delivery systems, newer vehicles of delivering drugs for better absorption and bioavailability. Examples of these are liposome's which serves as lipoidal vesicles (lipid bilayer), which act as drug carriers for improving the delivery for pharmaceutical drug. Liposomes are small lipoidal vesicles enclosing aqueous solution inside a hydrophobic membrane, in order to deliver the molecules to targeted site, the lipid bilayer can fuse with other bilayers such as the cell membrane, thus liposomes act as drug carrier for drug delivery[17]. Such vehicles for drug administration could be applied to other class of drugs to come out with newer NDDS for drugs under scrutiny for delayed mode of action of insignificant bioavailability.

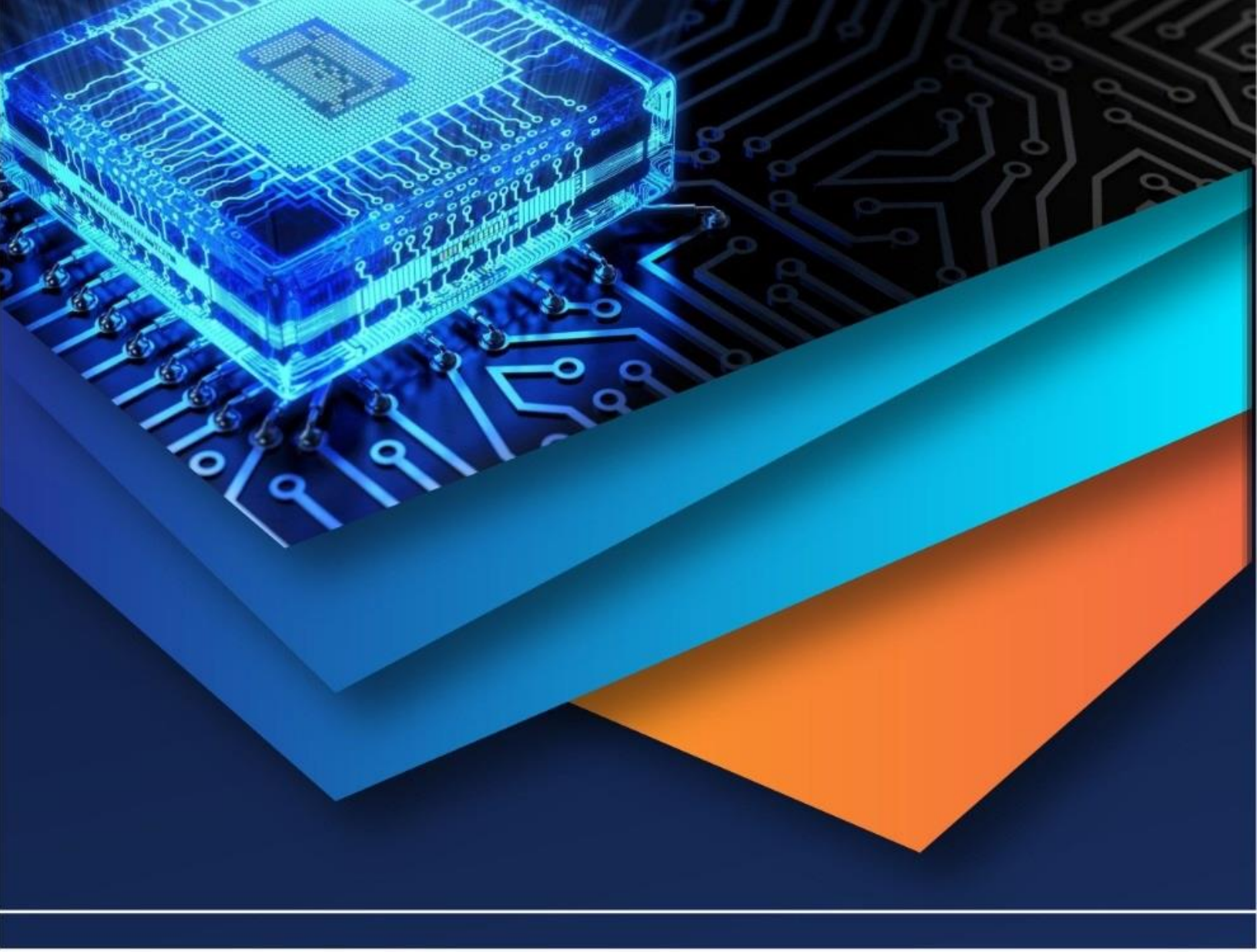
IV. RESULTS AND CONCLUSION

Worldwide many pharma majors have started affluent initiatives towards directing the research on discovering Novel Drug Delivery Systems to improve the performance of many drugs, this paradigm shift from working on new drug discovery to the discovery of newer drug delivery systems is shaping up very fast. As precursors for Novel drug delivery systems, research work much be encouraged on certain material with exceptional biocompatibility, to be used as vehicles for drug administration. Pharmaceutical companies must now focus on this opportunity of introducing NDDS as means of extending the life cycle of their noteworthy discoveries and survive with flying colors in this struggle for the survival of the fittest, and for providing additional revenue generation. To provide an impetus to the critically falling status of the sustainability of the pharmaceutical industry, this shift in focus could prove to be of paramount importance.

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