ISSN (Online) 2456 -1304

International Journal of Science, Engineering and Management (IJSEM)

Volume 11 Issue 8 August 2024

Introductions of Different Types of Pharmaceutical Formulation

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Abstract*— The development of pharmaceutical formulation is a make-or-brake system for the active pharmaceutical ingredients or APIs. During development stage, API is collaborated with excipients to select a particular dosage form. Several factors are required to be considered at the time of formulation. For this reason, it is necessary to have effective clinical trial of each drug, while formulation. This process is involved in modifying drug's chemical properties. The present work will shed light on issues of concern regarding pharmaceutical formulation, related clinical relevance of pharmaceutical formulations to ensure momentous impact on human life and proper intervention of allied health, nursing and interprofessional team. This can improve the process of pharmaceutical formulation.

Keywords: pharmaceutical formulation, APIs, development stage, chemical properties, healthcare, nursing, interprofessional team.

I. INTRODUCTION

A. Background, Motivation and Objective Background

Pharmaceutical formulation corresponds to a multistep process, in which active drug is assorted with other components through considering various aspects. This includes solubility, pH, features of particle size and polymorphism to produce helpful medicinal products. In this manner, various pharmaceutical products can be formed, including chemical properties of the drug, formulation of chemicals, and particulars of suitable treatment protocol, which is implemented in clinical application. Numerous medication formulations are there available in market for physicians for patients to prescribe and utilize therefore [1]. These pharmaceutical formulations have substantial fund, effort and time put in production to grouping of these medications. This helps to understand their working styles and test efficacy. Developed drugs can interact with various proteins in human body, but only some of them are the aims of medications to be developed [2]. This ensures future progress of various innovative drugs that can target residual proteins in human body.

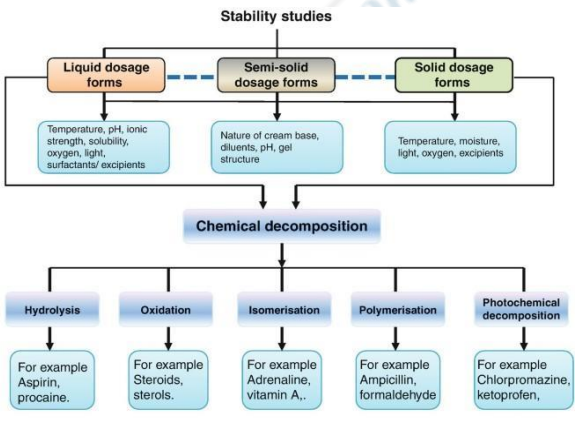

Figure 1. Stability of drug formulation

For example, the folate antagonist drug, Methotrexate (MTX) is generally used for different diseases, including cancers, inflammatory bowel, various malignancies and rheumatoid arthritis (RA). There are different types of formulations, such as liquid, tablet, capsules, Topical medicines, Suppositories, drops and inhalers, all of which are effective in recent days.

Due to having some relevant structural features, together with existence of 2 “carboxylic acid groups” and lower native fluorescence, several challenges can arise for its determination [4].

B. Motivation

Clinical significance of recent pharmaceutical formulations is high, as it has a great impact on human beings to a large extent, such as quality of their lives, outcomes of serious disease, and adherence to relevant treatment protocol. Furthermore, effectiveness of pharmaceutical medication corresponds to multitude factors, such as chemical properties of the medication, formulation of drugs and administration mode. Manufacturers of various pharmaceutical products have been vigorously investigating promising ingredients, which are added to formulations [2]. However, the drug is required to be steady and satisfactory to all patients. The primary consideration is acceptance of patients, while developing preparation.

Drug varies by administration of it at different circumstances and undistinguishable drugs can present different outcomes, depending on way of administrations. Some of the developed medications have exploited their efficiency, as they are used appropriately. Active therapeutic alternatives have become urgently required due to rising pandemic and other issues [3]. More complicated regimens demonstrate decreased compliance of the patient. Subsequently, it is essential to design a low-complexity treatment for with optimum effectiveness. However, there is burden to pharmaceutical industry to reduce healthcare cost and number of “active pharmaceutical ingredients” (APIs).

ISSN (Online) 2456 -1304
International Journal of Science, Engineering and Management (IJSEM)
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For combating this issue, it is necessary to determine anticipated formulations for this industry. This will be helpful to determine well-organized strategies to develop and formulate drugs.

C. Objective

Objectives of this research are mentioned below.

- To identify the issues of concern in regards to pharmaceutical formulation
- To determine clinical relevance of various types of pharmaceutical formulations to ensure momentous impact on human life
- To explore the intervention of allied health, nursing and interprofessional team in the process of pharmaceutical formulation

II. STATEMENT OF CONTRIBUTION/METHODS

A. Statement of Contribution

In this research work, A and B presented the idea of paper. C has developed the theoretical framework and documented the background information about pharmaceutical formulation. Once the background is outlined, D has decided the objectives of research, by addressing the issues of concern, clinical relevance and intervention of various professionals engaged in the process. E has collected some secondary materials from authentic databases and F gathered the information relevant to the subject matter. According to this, G has discussed the results found and drawn the conclusion.

B. Methods

a. Research philosophy

For continuing this paper, positivism philosophy has been adopted, which helped to pay attention to only the factual knowledge regarding the process of pharmaceutical formulation. This mainly relies on reason and measurement, for which knowledge has been revealed from quantifiable and neutral observation.

b. Research strategy

Descriptive strategy used in this research has helped the to focus on notional framework, for which different topics have been explored around this area. A better understanding of secondary data has been incorporated with this strategy.

c. Research method

For the present work, secondary method has been considered. In order to do this, a substantial number of reading materials have been collected that are based on previously existed journal articles. However, these materials are current, as they are not published before 2019. Furthermore, these second-hand materials have sound methodology and well-developed research aim and objectives. These secondary materials have utmost importance to provide a great insight about the subject matter.

III. RESULTS, DISCUSSIONS AND CONCLUSIONS

A. Results

Clinical relevance of pharmaceutical formulations

During the process of drug formulation, clinicians search solutions, which can be scalable in manufacturing. Stability is a vital factor for success of a particular drug. Medicines with compound formulations are problematic to scale, for which dedicated manufacturing facilities is needed for this. Such practice can impact availability and pricing of the drug [7]. Formulation of drug-related studies are continuing from early clinical trials. Once safety and efficacy are confirmed, clinical trials start, although formulations are being studied. There are various types of formulations in the field of medicine.

Among different types of pharmaceutical formulation, liquid is the most active part that have different natures, such as syrup, mixture or solution. When the active ingredient is shared with other substance and locked solid shape, it forms a tablet. Capsules contained in plastic shell. Other types of formulations, such as Topical medicines and suppositories and drops [19].

In this context, scientists determine a suitable way to achieve drug delivery in an effective way, on the basis of patient need. After this, they optimize characteristics of formulation according to the knowledge about bioavailability of the drug products and their processing requirements. For this reason, it consists of proper experiment regarding API, developed by “Food and Drug Administration” of USA [8]. Different functional categories are involved in this process, such as pH Modifier, tonicity agent, bulking agent, solubilizing agent, antioxidant, antimicrobial preservative and complexing agents.

Figure 2. Stages of pharmaceutical formulations

Due to fragility and complexity of active compounds, some challenges can exist in formulation of a drug. In this context, preservation and stability present substantial challenge, since API of biologic is highly unstable, compared to other small molecule drugs. Additionally, protein-built therapeutics cause immunogenic response, which lead to hostile events. These are not discovered until the medicine is arrived in the market [8]. For this reason, maximum medicines are developed in liquid form, as these are compatibility with intramuscular, intravenous or subcutaneous administration.

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For example, measured release formulations exploit capability of polymer or lipid-based aggregates within the solution of deliver, sequester and solubilize drugs. This is generally done in tuneable and controlled manner. “Modern GPU-based simulation” of “drug solutions model” plays an important role in formation and structurisation of these aggregates. This can also predict positioning of active molecules present in them. Reference to this matter, compared to small molecule in parent pharmaceutical ingredients, nanomedicines demonstrate complex and different pharmacodynamic and pharmacokinetic (PK) profiles, which have different efficacy [9]. This structure-based information is not easy to obtain from previous experiment. However, it is an imperative component for rational and structure-driven formulation.

Allied health, nursing and interprofessional team play a dynamic role in the process of pharmaceutical formulation

Developing a proper invention is mandatory with a non-complex procedure for patients to improve their outcomes by adhering to pharmaceutical formulations. Cooperatively, every constituent of patient care or healthcare team is related to their satisfaction. Recently, there is a great focus on patient’s fulfilment with medication, since it can generate a patient-reported outcome. Pharmaceutical care demands substantial efforts of patients, interprofessional team, informal caregivers, healthcare system administrators and healthcare professionals [5]. Developers also need to regulate formulation route, which is not a trial-and-error approach, but beyond that. Specialized treatment is required to lessen cost and labor associated with trial-and-error approach. This also improves adherence to patient’s regimens.

Patient compliance is therefore essential, which includes cautious collaboration of healthcare specialists engaged in healthcare organisation. This is crucial to ensure suitable execution of various pharmaceutical formulations. Physicians understand the core reason and the ways of medication interacting with human body. Effective communication within team and vibrant explanations of responsibilities are the central prerequisites to collaborate effectively among nurses, pharmacists and physicians [6]. They can provide quality care and meet patients’ requirements. Due to this matter, all the responsible team members, such as nurses, pharmacists, specialists and others try to maintain effective communication to display proper answerability, while administering this formulation. This helps to guarantee patients’ safety.

Challenges and the present issues in the field of pharmaceutical formulation

For pharmaceutical formulation, API is required to be efficacious and safe, however, the devices, excipients and primary packaging materials should be safe. Emphasis on drug formulations is mounting continuously, in order to advance the therapeutic effectiveness of active compounds, which can improve patient’s compliance [10]. Beforehand preliminary human trials, these formulations must efficaciously pass preclinical or animal trials, which helps to ensure efficacy and safety. Apart from knowledge of various formulation parameters, a proper understanding of physical and chemical characterization, toxicology and pharmacokinetics is demanding. After the process of physicochemical characterization development of formulation initiates.

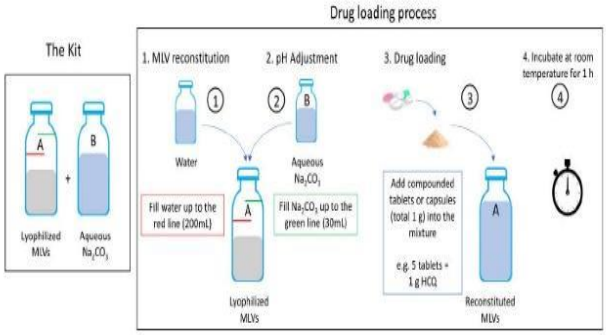

Figure 3. Pharmaceutical formulation for paediatric patients

This possesses various challenges in this field. Low solubility results in suboptimal efficiency of the drug and bad absorption, which increases the chance of having side effects. This also affects multiple factors such as pH levels, polarity, size of drug particles and its interaction with human body. The process of drug formulation corresponds to three stages, such as “synthesis, isolation and purification” and finally manufacturing of drug products [11]. First-pass metabolism occurs, while a pharmaceutical formula metabolizes “en route” to intended field of action. This creates various health issues in context of oral medication. Due to this matter, pharmaceutical industry faces several issues with safety of the paediatric patients and patent protection.

Bioavailability and the opportunities in the field of pharmaceutical formulation

A trend has been observed in progressive manufacturing technology across pharmaceutical sector, which has greater focus on efficient and more integrated processes, which are on-demand medicine, continuous manufacturing and others. All of these put never-ending effort to offer sustainable solutions in the pipeline digitalization and prediction of challenging compounds created a fast pace to predictive approaches, which has been supported by digital collaboration within pharmaceutical industry [12]. A rising count of biomolecules have been found in this pipeline, which brings additional opportunities, such as stability and protein purification.

Moreover, FDA sanctioned the switch to unremitting manufacturing of “Johnson & Johnson’s (J&J’s)/Janssen’s drug Prezista” from batch production in the year 2016. This is a significant landmark decision in this domain. Due to this, J&J/Janssen has been able to reduce manufacturing as well as its “clinical testing cycle time” by 80%. This also reduced

waste by 1/3rd, and abridged overall process. Moreover, 3D printing technology prints layer-by-layer, though which materials can be deposited based on its digital model by "computer aided design (CAD) software" [13]. Present technology helps to give a competitive advantage in regards to complexities in product design, on-demand manufacturing and product personalization.

IV. DISCUSSIONS

Pharmaceutical formulation is tremendously important in pharmaceutical industry, as this process generates suitable method for preparation of drug. Appropriate development of drug formulation ensures that manufactured pharmaceutical products are safe and these accessible to end-users. Advancement of particular systems of drug delivery cannot be feasible without employing polymer technology, since a rising number of polymeric materials were industrialized in this system over the last decade [14]. Due to this matter, formulation has a crucial role to devise manageable and practical strategies during development process. In new drug delivery system, various formulation strategies are deployed.

Due to this matter, all the healthcare workers, along with nurses and interprofessional team play contributory role in improving drug compliance. For implementing this, sharing knowledge, having open communication and considering collaborative decision-making are necessary. Development of Molecular dynamics has also paved this way [15]. This leads to better compliance with patients and provides optimal dosing. Regarding this matter, nature of patients' population as well as pharmacokinetic parameters specific to patients is necessary. This helps to promote medication with safety by interprofessional collaboration.

V. CONCLUSIONS

From the above discussion, it can be concluded that drug formulation results in many dosage forms, such as liquid, solid or semisolid, depending on patient needs and administration. Seldom, drug substances are managed as a part of large formulation combined to other ingredients. Excipients or pharmaceutical ingredients serve specialised and varied pharmaceutical functions. Recently a range of opportunities have been found to bring improvement in this field.

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