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DEVELOPING A NOVEL PHARMACEUTICAL FORMULATION FOR IMPROVING PATIENT COMPLIANCE

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ABSTRACT
In order to create a final, usable pharmaceutical product, the active ingredient is combined with all other constituents in a multi-step procedure that takes pH, solubility, polymorphism, and particle size into consideration. The formulation frequently works by mixing various dose forms. The pharmaceutical drug product that is marketed for use with a certain combination of active and inactive ingredients is referred to as the dosage form. It must be given in a certain dosage and have a certain form (capsule shell, for instance). Tens of thousands of different drug formulations are already available for use by doctors and patients. It has taken a lot of time and money to produce each of these pharmacological formulations in order to comprehend how the medications function and evaluate their effectiveness. Only a small percentage of the proteins in the human body are the targets of current pharmaceuticals, despite the fact that many of them are known to interact with them. This makes it possible to create future drugs that specifically target the body's remaining proteins.
Keywords: pharmaceutical drug, medication formulations, configuration

1. INTRODUCTION

The list of drugs aims to increase every year due to the substantial sum of money invested annually. However, the number of new molecular entities (NMEs) approved by the FDA each year does not increase much due to the uncertainty surrounding medicine design; as a result, the list stays the same [1]. Generally speaking, drug design requires that the target molecule that the medication will attach to or wish to interact with have a complimentary charge and shape [2]. It makes use of bioinformatics methods and computer modelling tools. A medicine must go through several stages before it can be marketed, including preclinical studies using animal and cell models and human clinical trials. Currently, trial-and-error techniques are used to generate pharmaceutical compositions [4]. Optimal formulations can be predicted with the aid of trial-and-error techniques. In addition to being costly and time-consuming, this procedure requires a great deal of work to design and oversee [11]. To counter this, the industry must identify the ideal formulations in order to come up with effective medication development methods. To guarantee safety and effectiveness, formulations must pass a number of preclinical (animal) experiments before beginning human trials. Formulation development starts when minimum physicochemical characterisation is completed [3]. Pharmaceutical formulations are clinically relevant because they significantly affect adherence to treatment, illness outcomes, and quality of life [6]. Furthermore, a number of variables, such as the chemical makeup, formulation, and manner of administration of a drug, affect how well a pharmaceutical treatment works. distinct routes of administration result in distinct drug forms, and the same medications can have different effects depending on how they are administered [8]. Proper use of such drugs has maximized their effectiveness. For optimal efficacy, a low-complexity regimen must be developed because more complicated regimens result in lower patient compliance [16].

2. IMPORTANCE OF THE STUDY

Each member of the patient care team works together to determine how satisfied the patient is with the treatment they get. As a patient-reported outcome, patient satisfaction with medication has received more attention in recent years [10]. To improve patient adherence to their regimens and reduce labor and costs associated with the trial-and-error method, developers must find a formulation route that is more specialized and not a trial-and-error

approach. In order to ensure that pharmaceutical formulations are implemented correctly, cooperation from all healthcare personnel is just as important as patient compliance [5]. The doctor must comprehend the drug's effects on the human body and why. To guarantee patient safety, nurses, pharmacists, and other crucial team members must also communicate effectively and demonstrate accountability while giving prescriptions [12].

Because it will increase patient noncompliance, which will ultimately cost pharmaceutical companies money, patients, who are the ultimate consumers through traditional means, and health care systems will not accept new drugs that do not meet consumer preferences or produce the desired results in real-world use. Research-driven pharmaceutical companies run the risk of misinterpreting patient needs, which might have serious financial repercussions, if they continue to ignore patient input throughout the development of novel drug formulations [13].

3. METHODOLOGY

Drug formulation is an important step in the drug development process since it directly affects a medication's safety, efficacy, and patient experience. A well-thought-out formulation ensures that the APIs are taken as prescribed, increasing their therapeutic efficacy and minimizing side effects [7]. following effective drug absorption at the absorption site, the transfer of a medication from an oral dosage form into the systemic blood circulation. For formulation absorption, several physicochemical properties are crucial, such as the permeability and solubility of the active component. Low solubility problems affect more than 40% of recently created unique chemical entities (NCEs). This is the primary barrier to creating a unique formulation that successfully releases the medication into the bloodstream. Development of oral Rapid dispersible/dissolving tablets are an alternative to the intraoral approach for blocking the absorption of medications through the GIT. The medicine can enter the systemic circulation right away by taking advantage of its rapid release in saliva and absorption through the oral mucosa [14]. However, this dosage form required a rapid and efficient release of the medicine into the oral mucosa. There are several physical and chemical methods that can be used to create such a formulation. An alternative to the conventional swallow tablet, dispersible tablets have a unique formulation that dissolves rapidly in water to provide a drinkable mixture. It combines precise dosing with the ease of swallowing and maybe enhanced absorption of a liquid formulation. A dispersible tablet may contain active components that are unstable in aqueous solution. There is less need for several formulations of the same medication because to the dispersible tablet's useful dose form. This greatly lowers development costs in the existing global health economy. The pharmaceutical industry now works in a setting where, in addition to efficacy and safety, containment costs and drug delivery optimization must be taken into account when a new drug product is licensed. The German Registration Authorities (BGA) have therefore supported the development of dispersible pills.

We examine recent developments in academic and business laboratories and offer professional insights in those contexts. To meet the demands of these new delivery modalities, formulation scientists have worked extremely hard. These include dosage forms and regimens that increase patient compliance, stability-maintaining formulations, and dehydration procedures.

4. SYSTEM DESIGN

Regretfully, they also bring with them fresh difficulties with manufacturing, storage, transportation, and stabilization. The vast majority of biologics now available on the market must be given parenterally due to their limited epithelial transport and low oral bioavailability [9]. The majority of these injectable formulations are liquids. It is commonly known that drugs in the solid state are frequently more stable than those in the liquid state, and that the differences are especially apparent in biological modalities because to their susceptibility to environmental factors.

Table 1: Participants profile

DP 1	Age of the Respondents					
	18-25 years	26-33 years	34-41 years	42-49 years	above 50 years	Total
Frequency	49	45	28	23	5	150
Percent	32.7	30.0	18.7	15.3	3.3	100.0

DP 2	Educational Qualification of the Respondents				
	certificate	diploma	bachelors	postgraduate	Total
Frequency	50	16	64	20	150
Percent	33.3	10.7	42.7	13.3	100.0
DP 3	Income Per Month of Respondents				
	12000-20000	21000-30000	31000-40000	41000-50000	above 50000	Total
Frequency	92	12	19	10	17	150
Percent	61.3	8.0	12.7	6.7	11.3	100.0
DP 4	Occupation of the respondents				
	Unemployed	Self-employed	private	government	Total
Frequency	74	52	21	3	150
Percent	49.3	34.7	14.0	2.0	100.0
DP 5	Marital Status			
	Married	Unmarried	Divorcee	Total
Frequency	90	58	2	150
Percent	60.0	38.7	1.3	100.0

Solution characteristics like pH, ion strength, oxidant content, and surface tension have a major influence on the stabilities of protein, bacteriophage, cell-living, and gene-delivery vehicle complexes. Product failure can also be easily caused by stresses that arise during the manufacturing, packing, handling, and storage processes, such as temperature changes, exposure to light while being stored, air-liquid interface tension brought on by agitation, and liquid-solid interface tension when contacting the package or filling apparatus [15].

Table 2: Frequency distribution of factor infusion

	Do you keep factors at home?					
	Always	Frequently	Sometimes	Rarely	Never	Total
Frequency	18	15	23	24	70	150
Percent	12.0	10.0	15.3	16.0	46.7	100.0
	Who infuses factors?					
	Myself	Technician	Relatives	Nurse	Doctor	Total
Frequency	10	14	14	97	15	150
Percent	6.7	9.3	9.3	64.7	10.0	100.0
	Are factors always available at Government Hospitals?					
	Always	Frequently	Sometimes	Rarely	Never	Total
Frequency	4	12	61	22	51	150
Percent	2.7	8.0	40.7	14.7	34.0	100.0
	Do medical professionals readily infuse factors?					
	Always	Frequently	Sometimes	Rarely	Never	Total
Frequency	12	37	50	35	16	150
Percent	8.0	24.7	33.3	23.3	10.7	100.0
	Has any medical professional ever refused treatment because of your haemophilia status?					
	Always	Frequently	sometimes	Rarely	Never	Total
Frequency	2	21	73	15	38	150
Percent	2.0	14.0	48.7	10.0	25.3	100.0
	Do you keep factors with you while travelling?					
	Always	Frequently	Sometimes	Rarely	Never	Total

Frequency	28	13	11	2	96	150
Percent	18.7	8.7	7.3	1.3	64.0	100.0
	Do you take physiotherapy?					
	Always	Frequently	Sometimes	Rarely	Never	Total
Frequency	11	21	45	22	51	150
Percent	7.3	14.0	30.0	14.7	34.0	100.0

Furthermore, hydrolysis is naturally induced by the presence of water. The comparatively delicate biological molecules or complexes may become unstable chemically and physically as a result of these pressures.

Table 3: Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	61.792a	12	0
Likelihood Ratio	57.119	12	0
Linear-by-Linear Association	32.953	1	0
N of Valid Cases	150		
9 cells (45.0%) have expected count less than 5. The minimum expected count is .53.			

Recent efforts have primarily focused on reformulating parenterally delivered biologics that have received FDA approval for patient-friendly, non-invasive administration methods. Pharmaceutical firms and patients gain from this reformulation: manufacturers overcome supply chain issues with cold chains, extend the patent life and market exclusivity of the reformulated products, and patients benefit from simpler administration, improved safety, reduced healthcare costs, and increased adherence.

5. CONCLUSIONS

In summary, the study effectively created a 1000 mg film-coated ranolazine tablet formulation that satisfies the desired goals of stability and efficient therapeutic delivery. The study emphasizes how crucial comprehensive reformulation and characterisation studies are to the creation of medicinal drugs. The findings support the possibility that extended-release formulations could enhance therapeutic efficacy and patient compliance, which would ultimately lead to better treatment of ailments like angina. The value of cooperation in attaining effective pharmaceutical development is further highlighted by acknowledgments of joint efforts and assistance from the Siddhant College of Pharmacy. Health care systems and patients, who are the final consumers in traditional ways, will not accept novel drugs that do not meet consumer preferences or have the desired effects in practical applications. Any small or large research-driven pharmaceutical industry that is unwilling to take into account the imperatives of patient adherence during the development of novel pharmaceutical dosage forms is likely to face increased risk and uncertainty; a low return on R&D investment; and the possibility that the developed products will not be able to meet the demands of patients, healthcare systems, government agencies, and regulators.

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