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EXPLORING THE EFFECTS OF EXCIPIENTS ON DRUG STABILITY AND BIOAVAILABILITY

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ABSTRACT

The physiognomies of the pharmaceuticals and the likelihood of consistent and repeatable clinical effects are typically the basis for a doctor's prescriptions. Nonetheless, it is typical for patients to respond differently to medications, which frequently makes it difficult to customize a dosage schedule for each patient. Drugs are frequently taken through a variety of ways, however the oral route is highly recommended because to its appropriateness, relative affordability, and high patient compliance rate. On the other hand, before oral dose forms may reach their precise site of action, they must dissolve in gastrointestinal fluids, absorb through intestinal epithelia, and undergo liver metabolism. The release of the active ingredient from the formulation, the rate of dissolution, the stability of the drug candidate in the gastrointestinal (GI) atmosphere, permeability, and metabolism in the gut wall and liver are some of the factors that contribute to the low and variable oral bioavailability because of this lengthy pathway.

Keywords: medication formulations, affordability, excipient functionality

1. INTRODUCTION

The pharmaceutical industry's declining research and development (R&D) efficiency over the past 20 years has become a global barrier to future growth and innovation for both R&D-based pharmaceutical businesses and generic medication producers [1]. The pharmaceutical industry's hesitancy and selectiveness in creating new medications are caused by years of development time and billions of dollars [2]. Thus, creating new formulations or adjustments of the current medications appears to be a sensible way to address the issues with the current medicinal products and partially satisfy the constant need for additional medications [4]. Value added generics (VAGs), sometimes referred to as super generics, are a method of creating new dosage forms for already-approved medications in order to provide quick, efficient, and problem-solving substitutes for traditional pharmaceutical goods that have certain drawbacks [11]. The shortcomings of the current drug goods are the unmet medical requirements that these generic drugs target [6]. VAGs are typically designed to be administered in different dose schedules or via alternative modes of administration than the current pharmacological products [8].

The number of drug candidates being developed has steadily increased in recent years due to developments in combinatorial chemistry, biology, and genetics [10]. A specific level of lipophilicity is frequently necessary for the medication molecule to not only be absorbed through the intestinal wall after oral administration but also potentially to exercise its pharmacological action in the target tissue because cell membranes are phospholipidic [3]. High lipophilicity naturally results in low water solubility, even though it is beneficial for compound permeability [12]. The vast majority of novel medication candidates are poorly soluble in water. In pharmaceutical drug formulation, poorly soluble medications are a common issue.

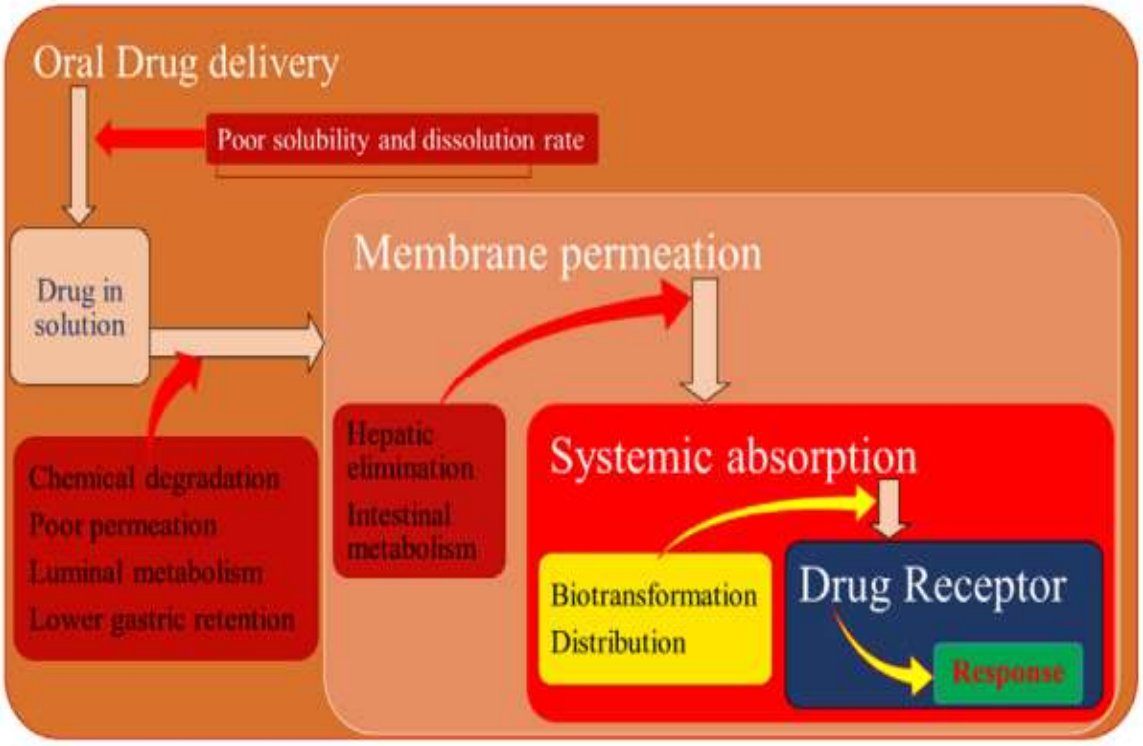

Figure 1: Factors influencing bioavailability of drugs in oral drug delivery

Too low bioavailability and/or irregular absorption are common issues with poorly soluble medications. In many situations, parenteral delivery is unable to address the issue of an excessively low bioavailability following oral administration. Intravenous injection as a solution is not feasible due to the poor solubility [16]. Due to an inadequate solute volume at the injection site, parenteral administration of a micronized product may not always result in adequately high drug levels. Pharmaceutical scientists are continuously looking for innovative formulation techniques to provide an appropriate oral bioavailability because of the growing number of compounds that come from discovery programs that have poor water solubility and/or dissolution. Today, the quickly developing field of nanoscience offers new opportunities.

2. BACKGROUND OF THE STUDY

When compared to standard formulations, NSs effectively increase the oral absorption of poorly soluble medications and obtain a better bioavailability. higher dissolution velocity, higher saturation solubility, surface modification adaptability, and ease of post-production processing are some of the main benefits of NS technology [5]. By adhering to the gastrointestinal mucosa, NSs increase the drug's contact time and, consequently, its absorption through the gastrointestinal tract (GIT). A precise selection of stabilizers is necessary for the formulation of NS. In order to stabilize the nanoparticles against inter-particle interactions and stop them from aggregating, stabilizers are required. At the nanoscale level, dispersion or van der Waals forces cause particles to be attracted to one another [13]. As the particles get closer to one another, this attractive force grows significantly, leading to an irreversible aggregation. Repulsive forces are required in order to overcome the attractive interaction. Steric stabilization and electrostatic stabilization are the two ways that repulsive forces or energetic barriers can be applied to a colloidal system. The process of adsorbing polymers onto the particle surface results in steric stabilization [7]. The osmotic stress produced by the encroaching steric layers keeps the particles apart as they get closer to one another. Adsorbing charged molecules—such as charged polymers or ionic surfactants—onto the particle surface results in electrostatic stability. An electrical potential barrier that prevents particle aggregation is provided by charge repulsion. For an extra repulsive effect, steric stabilization is frequently coupled with electrostatic stabilization. [14].

3. METHODOLOGY

At the moment, almost 60% of medications are sold as oral preparations. The aforementioned considerations make it impossible for these medications to be administered orally in their original form. One of the most difficult objectives in oral medicine delivery at the moment is removing these obstacles. [9-10].

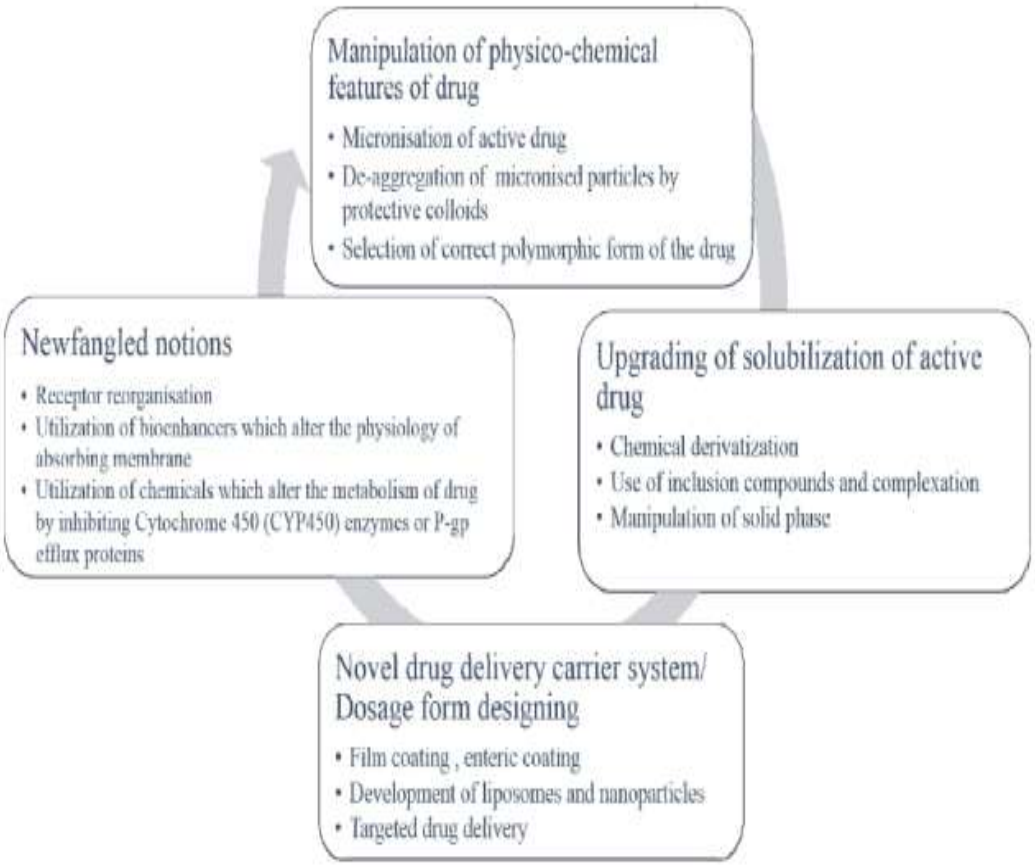

Figure 2: Various Strategies to improve bioavailability of drugs

Numerous tactics have been used to increase a drug's bioavailability following oral administration. The solutions listed below can be used either alone or in combination to address the issue of low bioavailability. An important part of developing a formulation is choosing excipients that work well with the active component [15]. A variety of analytical techniques must be applied to ensure the quality and effectiveness of the finished pharmaceutical products. When choosing excipients logically, it is crucial to apply ideas, thermal methods, and compatibility assessment. Despite the fact that several of these methods have shown promise in laboratory-scale studies, they continue to pose problems with regard to long-term safety and reproducibility in clinical settings. Even a number of advanced new drug delivery techniques have been tried to increase bioavailability, which has little market potential because of its instability and high manufacturing costs.

4. SYSTEM DESIGN

Excipients are assessed in relation to drug products; they are not authorized or licensed separately. Instead, excipients present in medications that have FDA approval are regarded as FDA-approved.

Table 1: Interventions and prevention

Items	Intervention	Control	p- value*
Physical	1 (0 − 2)	0 (-1 − -2)	0.378

Psychological	1 (0 − 2)	1 (0 − 3)	0.614
Level of independence	1 (-1 − 3)	1 (0 − 3)	0.369
Social relationships	3 (1 − 4)	2 (0 − 4)	0.679
Environmental	2 (0 − 4)	2 (0.75 − 4)	0.739
Spirituality	1 (-1 − 3)	0 (-2 − 2)	0.061

FEMA evaluates flavoring agents independently. The FDA encouraged excipient makers to submit applications for FDA assessment of novel excipients before their duration of exposure or mode of administration when the program was voluntarily implemented on September 7, 2021.

Table 2: Inter Physician agreement

Physician1	Physician2		Total	Kappa Value	P Value
	Yes	No			
Yes	108	7	115	0.824	0.004
No	10	4	14		
Total	118	11	129		

Excipients are chosen based on their intended usage, safety, and effectiveness. The FDA, the European Medicines Agency (EMA), and other regulatory agencies determine an excipient's regulatory status, which serves as the foundation for the selection criteria. In different nations and areas, excipients have varying regulatory statuses.

Table 3: Individual differences and contextual factors

Items	Intervention	Control	p-value*
Physical	1 (0 − 3)	0 (-1 − 2)	0.039
Psychological	4 (2 − 5)	3 (1 − 5)	0.115
Level of independence	2 (0 − 4)	1 (-1 − 4)	0.085
Social relationships	3 (2 − 5)	2 (0.7 − 4)	0.013

Environmental	4 (2 − 5)	3 (1 − 5)	0.032
Spirituality	3 (1 − 5)	1.5 (-0.2 − 1.5)	0.006

For example, China implemented the co-review process for excipients in December 2017. In compliance with the CFDA notification, all pharmaceutical excipient manufacturers and owners, whether domestic and international, must submit their dossiers to the CDE. No.

Table 4: Inter Tool agreement

New VA Tool	**WHO Tool**		**Total**	**Kappa Value**	**P Value**
	Yes	**No**			
Yes	**57**	**1**	**58**	**0.576**	**< 0.001**
No	**4**	**4**	**8**		
Total	**61**	**5**	**66**		

The selection criteria are also influenced by the planned usage of the excipients. When selecting excipients, the three primary considerations are the Active Pharmaceutical Ingredient's (API) compatibility, stability, and potential to enhance drug delivery.

Table 5: Mental health outcomes

Items	**Intervention**	**Control**	**p- value***
How do parental social media use and monitoring influence youth mental health outcomes?	1 (-1 − 3)	0 (-2 − 2)	0.079
What impact does social media have on teenagers' self-esteem and self-concept?	3 (1 − 4)	2 (0 − 3)	0.007
How does social media use relate to suicidal ideation and behaviors in youth?	1 (0 − 3)	0 (-2 − 2)	0.001
What are the disparities between urban and rural youth's use of social media and mental health outcomes?	2 (0 − 3)	0 (-1 − 2.2)	0.027

How can social media platforms be designed to promote positive mental health outcomes in youth?	2 (1 − 4)	1 (0 − 2)	0.001
What connection exists between youths' use of social media and signs of anxiety and depression?	2 (0 − 4)	1 (-1 − 3)	0.126

Excipients are selected based on their safety and effectiveness. Additionally, nano emulsions may advance the actives' challenging organoleptic qualities or provide a convincing level of protection against degradation. Certain nano-emulsions are exceptional for oral formulations because they have a propensity to self-emulsify in aqueous environments.

5. CONCLUSIONS

The liquid lipid was substituted with a solid lipid, which ultimately changed into solid lipid nanoparticles, in order to get around the drawbacks of the oil droplets' liquid nature. Small size, vast surface area, high drug loading, and phase interaction at the interface are some of the distinctive qualities that SLN offers. They are also appealing because of their potential to enhance pharmacological efficacy. Site-specific drug delivery is made biologically possible by reduced size and narrow size distribution. Formulations have been shown to affect intestinal penetration of medications that are delivered both transcellularly and paracellularly. Therefore, they can be applied to actives that have limited solubility, low permeability, or a combination of the two issues.

REFERENCES

1. Ruiz-Picazo, Alejandro, Isabel Lozoya-Agullo, Isabel González-Álvarez, Marival Bermejo, and Marta González-Álvarez. "Effect of excipients on oral absorption process according to the different gastrointestinal segments." *Expert Opinion on Drug Delivery* 18, no. 8 (2021): 1005-1024.
2. Duhaim, S. M., Taleb, D., &Ghadhban, Z. H. (2024). The Quality Learning System Interface Factor of Success Blended Learning. *International Academic Journal of Science and Engineering*, *11*(1), 262–264. https://doi.org/10.9756/IAJSE/V11I1/IAJSE1130
3. Ugale, Shweta, and Kaveri M. Nannor. "THE ROLE OF EXCIPIENTS IN ENHANCING DRUG DELIVERY AND STABILITY: A COMPREHENSIVE REVIEW." (2024).
4. Sen, V., & Malhotra, N. (2025). A Critical Analysis of the Education for Sustainable Development. *International Journal of SDG's Prospects and Breakthroughs*, *3*(1), 22-27.
5. Van der Merwe, Jannes, Jan Steenekamp, Dewald Steyn, and Josias Hamman. "The role of functional excipients in solid oral dosage forms to overcome poor drug dissolution and bioavailability." *Pharmaceutics* 12, no. 5 (2020): 393.
6. Bhattacharya, R., & Kapoor, T. (2024). Advancements in Power Electronics for Sustainable Energy Systems: A Study in the Periodic Series of Multidisciplinary Engineering. In *Smart Grid Integration* (pp. 19-25). Periodic Series in Multidisciplinary Studies.
7. García-Arieta, Alfredo. "Interactions between active pharmaceutical ingredients and excipients affecting bioavailability: impact on bioequivalence." *European Journal of Pharmaceutical Sciences* 65 (2014): 89-97.
8. Balvad, K., Lalit, D., Re-Ann, C., Halimpusan, T., & Beyes, J. O. (2022). Unveiling 4G LTE: Revolutionizing connectivity in the digital age. National Journal of Antennas and Propagation, 4(1), 41–46.
9. Omari, Derar M., Yazan Akkam, and Assayed Sallam. "Drug-excipient interactions: an overview on mechanisms and effects on drug stability and bioavailability." *Annals of the Romanian Society for Cell Biology* 25, no. 4 (2021): 8402-8429.
10. Sadulla, S. (2024). Next-generation semiconductor devices: Breakthroughs in materials and applications. Progress in Electronics and Communication Engineering, 1(1), 13–18. https://doi.org/10.31838/PECE/01.01.03
11. Jackson, Kimberley, David Young, and Sonia Pant. "Drug–excipient interactions and their affect on absorption." *Pharmaceutical science & technology today* 3, no. 10 (2000): 336-345.

12. Lucena, K., Luedeke, H. J., & Wirth, T. (2025). The evolution of embedded systems in smart wearable devices: Design and implementation. SCCTS Journal of Embedded Systems Design and Applications, 2(1), 23–35.
13. Zarmpi, Panagiota, Talia Flanagan, Elizabeth Meehan, James Mann, and Nikoletta Fotaki. "Biopharmaceutical understanding of excipient variability on drug apparent solubility based on drug physicochemical properties. Case study: Superdisintegrants." *The AAPS journal* 22 (2020): 1-17.
14. Panakanti, Ravikiran, and Ajit S. Narang. "Impact of excipient interactions on drug bioavailability from solid dosage forms." *Pharmaceutical research* 29 (2012): 2639-2659.
15. Comoglu, Tansel, and Emine Dilek Ozyilmaz. "Pharmaceutical excipients in pediatric and geriatric drug formulations: safety, efficacy, and regulatory perspectives." Pharmaceutical Development and Technology 30, no. 1 (2025): 1-9
16. Panakanti, Ravikiran, and Ajit S. Narang. "Impact of excipient interactions on drug bioavailability from solid dosage forms." In Excipient Applications in Formulation Design and Drug Delivery, pp. 273-310. Cham: Springer International Publishing, 2015.
17. Surendar, A. (2024). Survey and future directions on fault tolerance mechanisms in reconfigurable computing. SCCTS Transactions on Reconfigurable Computing, 1(1), 26-30. https://doi.org/10.31838/RCC/01.01.06
18. Arthur, L., & Ethan, L. (2025). A review of biodegradable biomaterials for medical device applications. Innovative Reviews in Engineering and Science, 3(1), 9–18. https://doi.org/10.31838/INES/03.01.02
19. Yaremko, H., Stoliarchuk, L., Huk, L., Zapotichna, M., & Drapaliuk, H. (2024). Transforming Economic Development through VLSI Technology in the Era of Digitalization. Journal of VLSI Circuits and Systems, 6(2), 65–74. https://doi.org/10.31838/jvcs/06.02.07
20. Sindhu, S. (2024). RFID-based asset tracking system using beam-steerable antennas for enhanced range and accuracy. National Journal of RF Circuits and Wireless Systems, 1(1), 28–38.
21. Madhanraj. (2025). Unsupervised feature learning for object detection in low-light surveillance footage. National Journal of Signal and Image Processing, 1(1), 34–43.
22. Abdullah, D. (2025). Environmental sound classification using CNNs with frequency-attentive acoustic modeling. National Journal of Speech and Audio Processing, 1(1), 8–14.
23. Shrirao, N. M. (2024). Intelligent design automation in VLSI systems: Leveraging AI for future electronics applications. Electronics, Communications, and Computing Summit, 2(3), 28–39.
24. Punam, S. R. (2024). Reconfigurable intelligent surfaces: Enabling spectrum-efficient and adaptive communication for 6G wireless networks. Electronics, Communications, and Computing Summit, 2(3), 49–57.