# A SYSTEMATIC REVIEW ON NOVEL EXCIPIENTS

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## ABSTRACT

*Excipients are additives used to turn active drug ingredients into forms that can be safely and effectively given to patients. New and improved excipients are being developed to help deliver drugs better. Synthetic polymers are popular because they can be customized by design, allowing for specific properties to be added or adjusted as needed. However, natural excipients are especially interesting because they are reliable, sustainable, and don't rely on fossil fuels. Plant-based excipients are appealing since they are compatible with the body, have low toxicity, are environmentally friendly, and are often cheaper than synthetic alternatives. They are also renewable resources, making them a sustainable option for producing affordable medicines.*

*Novel excipients are essential for creating modern drug delivery systems and biotechnology- based drugs. However, despite many new excipients being developed, they aren't commonly used in medicines. This is because of strict regulatory requirements and the perception that adding new excipients complicates the product evaluation, potentially delaying approval.*

*Regulators treat novel excipients as new substances, so each new excipient in a drug formulation must go through a full evaluation process similar to that of a new active ingredient. As a result, much more detailed and complex information is needed for regulatory approval (marketing authorization) compared to established excipients. This review gives an overview of the novel excipients used in medicinal products approved in the European Union. It also explores the challenges in developing new excipients and discusses possible ways to address these obstacles.*

*A novel excipient is a new substance that hasn't been used in any approved drug. However, pharmaceutical companies are often hesitant to use novel excipients due to the risk that regulatory authorities might not approve the drug because of the new ingredient. Additionally, companies worry about whether these novel excipients can be consistently supplied from production facilities that meet GMP (Good Manufacturing Practice) standards.*

*The USFDA encourages innovation in excipients to support new drug development and improve existing treatments. The IPEC (International Pharmaceutical Excipients Council) also works to promote the acceptance of these new excipients in the market.*

*The goal of this research is to evaluate different polymers as novel excipients for developing effective drug forms. These new excipients were tested for their abilities as agents that can enhance drug delivery, break down skin barriers, or act as biological reagents. The research also examined their physical and chemical properties, as well as the regulatory requirements for their use.*

*Pharmaceutical formulation is constantly advancing, driven by the need for better drug delivery methods and improved treatment results. A key part of this progress is the development and use of novel excipients. This review looks at the different types and examples of these new excipients that have transformed drug formulation in recent years. It examines their uses, benefits, and limitations, emphasizing how important they are for the future of pharmaceutical formulation. Using these innovative materials not only makes drugs more effective and easier for patients to take but also opens up new possibilities for personalized medicine and targeted drug delivery.*

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***KEYWORDS***-*Novelexcipient, denimers,co-polymers Surface active Novel excipients,Novel Excipients types, Regulation,Challenges, Soluplus, Eudracap*

## INTRODUCTION

Over the years, excipient suppliers have created new combinations and forms of excipients to meet the demands of modern drug delivery methods, like skin patches, inhalers, and slow-release tablets. However, most

companies focus on improving existing excipients rather than creating entirely new ones, as strict regulations make it challenging to bring new excipients to the market.

In the U.S., excipients must pass one of three approval routes by the FDA to be used in approved drugs:

1. Generally Recognized as Safe (GRAS): An excipient can be approved if it is already recognized as safe based on historical use.
2. Food Additive Petition: Approval as a food additive.
3. New Drug Application (NDA) Reference: Approval through a specific drug application where the excipient's role in a product is documented.

The International Pharmaceutical Excipients Council (IPEC) has grouped excipients for solid dosage forms (like tablets) into 13 categories based on their function. These categories include:

Binders: Help hold ingredients together.

Disintegrants: Help tablets break down in the body. Fillers: Add bulk to the tablet.

Lubricants: Prevent ingredients from sticking during production. Glidants: Improve powder flow during manufacturing. Compression Aids: Help shape the tablet.

Colors and Sweeteners: Improve appearance and taste. Preservatives: Prevent contamination.

Suspending/Dispersing Agents: Help particles spread evenly. Film Formers/Coatings: Add a coating to protect the tablet.

Flavors and Printing Inks: Improve taste or add printed information.

Research has shown that using new types or roles of excipients can make drugs work better. Pharmaceutical excipients are essential ingredients in medicines, even though they are generally considered inactive. They play a critical role in making sure the medicine is safe,

effective, and acceptable for patients. For example, excipients can:

Protect the active ingredients: Some excipients, like antioxidants and stabilizers, keep the main drug stable and prevent it from breaking down.

Prevent contamination: Preservatives stop the growth of harmful microbes in medicines during storage.

mprove drug effectiveness: Certain excipients help the drug be absorbed better in the body or control how fast it's released, such as solubilizers and penetration enhancers.

Make medicines easier to take: Flavors and sweeteners make oral medicines taste better, while buffer salts can make injections more comfortable.

In the European Union, excipients are defined as any part of the medicine that isn't the main active ingredient or the packaging. Excipients come in many types and have different functions, origins, and structures, such as natural vs. synthetic or single chemicals vs.

mixtures.

While excipients were once mostly well-known and commonly listed in reference books like pharmacopoeias, there is a growing demand for more advanced excipients designed for specific tasks. New technologies and the need for more targeted drug delivery have led to the creation of novel excipients. These new excipients are especially important for modern

medicines, including biotech drugs, as they help create more sophisticated and efficient drug delivery systems.

Excipients make up the largest part of most modern pharmaceutical formulations. The International Pharmaceutical Excipients Council (IPEC) defines excipients as ingredients, other than the active drug, that have been carefully tested for safety and are intentionally added to support the drug delivery system. These substances help improve the stability, bioavailability, patient experience, and effectiveness of the medication by performing important technical roles.

An excipient is an inactive substance that helps deliver a medication. Excipients make up most of a pill, liquid, or other medicine form, adding bulk for accurate dosing, making the

medicine easier to handle during production, and helping stabilize the active ingredient so

it lasts longer. Different excipients are used depending on how the medicine is given — like tablets for swallowing or suppositories for rectal use. Excipients also improve the taste and texture and help ensure the active ingredient reaches the right place in the body at the right time. Every medicine includes excipients, each with a specific purpose.

**TYPE OF EXCIPIENTS**

**1) BASED ON ORIGIN**

ANIMAL
VEGETABLE
MINERAL

**2) BASE ON THEIR FUNCTION**

LUBRICANT
DILUENT

**TYPES OF NEW EXCIPIENTS**

TYPE OF NEW EXCIPIENTS

1.Modified Excipient

Modified excipients are those whose physical characteristics, such as particle size, shape, and structure, are adjusted to meet specific needs. While their chemical composition, which affects safety and toxicity, is hard to change, physical properties can be tailored for specific applications. For example, excipients like lactose, mannitol, and microcrystalline cellulose come in various grades suited for different uses. These modifications can improve handling and product performance. Stricter regulations and customer demands for higher-quality excipients have driven improvements in purity and customization, reducing unwanted reactions and enhancing drug stability.

2.Co-processed Excipient

Co-processed excipients are created by combining two or more known excipients in a way that improves their physical and functional properties. Unlike simple mixing, co-processing involves methods like granulation or spray drying to create excipients with enhanced performance. These excipients simplify the manufacturing process, reduce costs, and improve efficiency by reducing the number of materials and steps needed. They are commonly used in tablet coating and direct compression, speeding up the development and production of new drugs.

3.Novel Excipient

A novel excipient is a completely new substance or one being used for the first time in a drug product or a new delivery method. These excipients require detailed analysis to ensure safety and stability, as they have no prior history of use in humans. Their chemical properties, impurities, and stability must be thoroughly studied before approval. This ensures that they meet safety standards while offering innovative solutions for drug formulations.

**NOVEL EXCIPIENTS**

A "novel excipient" is a new type of inactive ingredient that hasn't been used before in any approved medicine or for a new way of taking the medicine (like a different route of administration). According to the FDA, a novel excipient is one that has never been approved in a drug or food product. Currently, unless a company includes it in a new drug application
(NDA) or investigational study, the FDA doesn't assess the safety of these novel excipients.

Because of this, drug companies are asking the FDA to create new ways to review and approve these innovative excipients, as they could improve how drugs are delivered, help prevent drug abuse in certain formulations, and offer other health benefits. If the FDA accepts a novel excipient, it provides drug companies with more confidence to use it, knowing it meets safety standards. To address this, the FDA has started a pilot program to review the safety and quality of these new excipients.

Some excipients, even if they're used in new ways, don't need the full range of safety tests recommended by the FDA. However, companies making these excipients or drugs must
carefully understand what tests are needed by the FDA when submitting a drug for approval. Misjudging the requirements can lead to long delays in getting a drug approved.

**ADVANTAGES**

1. Better drug absorption and solubility: New excipients can help medications that don't dissolve well in water to become more soluble, which improves how much of the drug is absorbed by the body.

2. Enhanced drug stability: New excipients can protect drugs from being damaged by things like oxygen, light, heat, and moisture, which helps the medication last longer on the shelf.

3. Controlled drug release: Excipients can be designed to release the drug at a specific rate, which is helpful for medications that need to be delivered over time or at a steady pace.

4. Taste and smell masking: Excipients can hide unpleasant tastes or smells of some drugs, making them easier and more pleasant for patients to take.

5. Fewer side effects and better patient compliance: New excipients can reduce some side effects, which may help patients stick to their prescribed treatments.

6. Flexibility with different forms of medicine: These excipients can work in various types of medicine forms, like tablets, capsules, or liquids, making it easier to develop different formulations.

**DISADVANTAGES**

1. Lack of regulations: There are no clear rules for new excipients, which can make it harder to get approval for drugs using them. This could delay the development of new medications.
2. Safety concerns: The long-term safety of new excipients might not be well understood. There could be unexpected side effects or interactions that are only found after more testing or once the product is on the market.
3. ource variability: It can be harder to find new excipients consistently. Differences in quality and availability can affect the quality and effectiveness of the medication.
4. Higher costs: New excipients might be more expensive to create and obtain, which can increase the cost of making the drug and make it more expensive for patients.
5. Manufacturing challenges: Some new excipients might require special equipment or manufacturing processes, which can make production more complicated and costly.
6. Compatibility issues: It can be hard to predict how new excipients will interact with the drug and other ingredients. If they don't work well together, the drug might not be stable or effective.
7. Intellectual property problems: Developing new excipients can be expensive, and it can be hard to protect the ideas behind them, especially if other companies come up with similar excipients independently.
8. Limited data: Since new excipients are innovative, there might not be enough data on their safety, stability, and effectiveness, making it difficult to understand the potential long- term risks.

**APPLICATION ON NOVEL EXCIPIENTS**

1. Improved Solubility
2. Sustained and control release
3. Taste Masking
4. Drug Stability
5. Enhanced Drug Targeting
6. Incorporation of Biologics
7. Gene Delivery
8. Nano Particle formulation
9. Personalised Medicine
10. Modified Released System
11. Oral Thin Film
12. Nano medicine

**CONCLUSION**

Developing and using new excipients is difficult because testing them for safety is costly and takes a lot of time. Setting up a Master File system in the EU and providing clear guidelines for developing and using novel excipients could help reduce these barriers. This would support innovation in drug delivery and make it easier to use new excipients. In summary, the field of pharmaceutical formulation is about to experience a major shift, thanks to the development of new substances, called excipients, which are added to drugs to improve their effectiveness. This review has looked at how these novel excipients work,

what benefits they offer, and what challenges they face. By using these innovative ingredients, drug makers can create medicines that are more effective and easier for patients to take. These advances also open up possibilities for customized treatments that better meet each person's unique needs. In short, adding these new excipients is a big step toward making safer, more effective, and patient-centered medicines. As research in this area grows, we're likely to see.

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