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Original Article

Liquisolid Compacts: A Paradigm in Drug Delivery System

Priya Patil*, Dr. Bharat Tekade, Dr. Mohan Kale

Department of Pharmaceutics, Konkan Gyanpeeth Rahul Dharkar College of Pharmacy and Research Institute, Karjat

ABSTRACT

Liquisolid compacts (LSCs) are a fascinating drug delivery technology that offers numerous advantages, particularly for Biopharmaceutical Classification System (BCS) class 2 drugs. In essence, they convert liquid medications into free-flowing, compressible powder forms suitable for tablet production with improved drug release characteristics. Formulation of liquisolid compacts represents a valuable strategy in overcoming solubility challenges, ultimately contributing to the development of effective and patient-friendly drug delivery system. This paper reviews the key components and the formulation process involved in developing liquisolid compacts. The improved wettability of the drug and the increased surface area of the molecularly dispersed drug in the liquid environment contribute to enhanced solubility. Pre- and post-compression tests are performed to optimize liquisolid compacts. Solid-state characterization studies (FTIR, DSC, SEM, PXRD) ensure drug-excipient compatibility. Accelerated stability studies demonstrate the safety and stability of liquisolid formulations over time. Thus, exploring different techniques and excipients can boost the pharmaceutical industry in designing stable and efficacious liquisolid compacts.

Keywords: Liquisolid Compacts, Quality by Design, Central Composite Design

INTRODUCTION

Liqui Solid Compacts are stable and cohesive mixture encompassing liquid and solid components in a way that results in a single tablet. The incorporation of excipients, such as carriers, binders, and disintegrants, plays a crucial role in achieving a balanced and effective formulation. The key components in the formulation, including the liquid medication, powdered excipients, and coating materials, play crucial roles in achieving the desired properties of the liquisolid compact [1-3]. The incorporation of DoE and QbD approach along with Central Composite Design can bring about a more definite formulation by consideration of multiple factors and variables affecting the formulation.

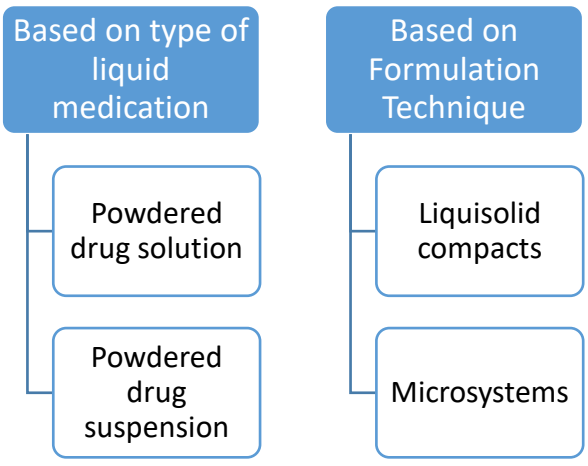

Figure 1: Classification of Liquisolid Compacts [7]

Benefits of LSCs:

- Enhanced dissolution: By finely dispersing the drug within the liquisolid system, LSCs can significantly improve drug dissolution rate and bioavailability, especially for poorly-soluble drugs [4]. By converting liquid drugs into dry, free-flowing powders, liquisolid systems increase the

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

wetting properties and surface area of the drug, leading to enhanced dissolution rates

- Controlled release: By using specific excipients and formulating strategies, LSCs can also be designed for sustained or modified drug release [5]. Liquisolid compacts offer the flexibility to tailor drug release profiles by using suitable formulation excipients. By incorporating hydrophobic carriers for sustained release or surface-active agents for improved wettability, liquisolid systems can achieve specific release characteristics based on the formulation requirements
- Improved stability: LSCs can offer better protection against drug degradation compared to pure liquids [6]. The liquid medication in liquisolid compacts can be protected from degradation by moisture or air exposure. This can be especially important for drugs that are sensitive to these environmental factors
- Cost-effective: LSCs utilize simple excipients and standard manufacturing processes, making them a cost-effective drug delivery option. Manufacturing liquisolid compacts is generally more cost-effective compared to soft gelatin capsules. The production cost of liquisolid systems is lower, making them an economically viable option for enhancing drug dissolution and bioavailability [7].

Components:

Carrier Material: This forms the backbone of the liquisolid compact, providing structure and facilitating compression into tablets. It's typically a high-porosity, high-compression material with a large surface area. Common choices include:

Microcrystalline Cellulose (MCC): The most widely used carrier due to its excellent compressibility, good flowability, and inert nature.

Starch: Another popular option with good compressibility and can be chosen based on desired disintegration properties (e.g., pregelatinized starch for faster disintegration).

Lactose: A cost-effective option with good flowability, but may have limitations for moisture-sensitive drugs.

Amorphous Cellulose: Offers high surface area for drug adsorption and potentially faster drug release [8,10].

Coating Material: This component plays a crucial role in absorbing and retaining the liquid medication within the compact. It's usually a fine, highly adsorbent material with a large surface area. Common choices include:

Colloidal Silicon Dioxide (Colloidal Anhydrous Silica): The most widely used coating material due to its high surface area, excellent adsorption capacity, and good flowability. Different grades with varying pore sizes can be chosen for specific drug-liquid medication combinations.

Microcrystalline Cellulose: Can also be used as a coating material in some cases, particularly when combined with colloidal silicon dioxide for a synergistic effect [9,11].

Liquid Medication: This is the core component containing the drug. It can be:

Drug Solution: The drug is dissolved in a suitable non-volatile solvent like propylene glycol or polyethylene glycol.

Drug Suspension: For drugs with limited solubility, a fine drug suspension in a non-volatile solvent can be used.

Emulsion: In some cases, an oil-in-water emulsion may be employed, especially for lipophilic drugs [12].

Formulation: Formulation Process:

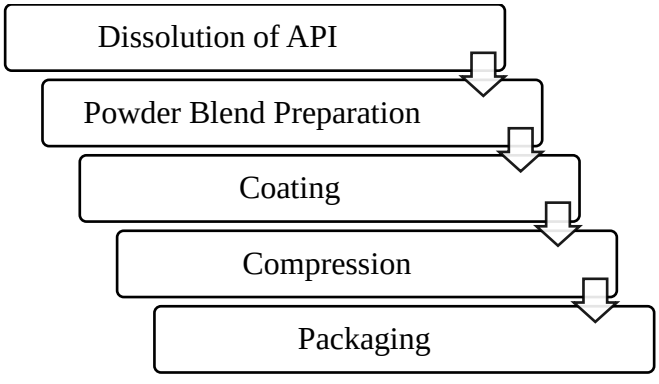

Figure 2:Stepwise methodology of Liquisolide Compact Preparation [19]

Steps of Formulating LiquiSolid compacts

Dissolution of API:

Dissolve or disperse the poorly water-soluble drug in the selected liquid vehicle. The choice of solvent depends on the solubility of the drug [13].

Powder Blend Preparation:

Mix the liquid medication with the powdered excipients to form a homogenous, free-flowing powder blend. The liquid is absorbed by the carrier material. Mixing Technique involves

A. **Geometric Mixing**:

Method: Geometric mixing involves blending the drug, liquid vehicle, and carrier material to create a homogenous mixture.

Advantages:

Simple and straightforward process.

Minimal equipment requirements.

Suitable for low-dose formulations.

Limitations:

Limited drug loading capacity due to carrier limitations.

May result in poor flow properties.

Application: Geometric mixing is commonly used for small-scale or lab-scale preparations.

B. **Wet Granulation**:

Method: Wet granulation involves wetting the drug and carrier particles with a liquid binder, followed by granulation and drying.

Advantages:

Improved flowability and compressibility.

Enhanced drug loading.

Better content uniformity.

Limitations:

Requires additional processing steps (granulation and drying).

May involve use of solvents.

Application: Wet granulation is suitable for larger-scale production.

C. **Coevaporation**:

Method: Coevaporation combines the drug and liquid vehicle by evaporating the solvent under controlled conditions.

Advantages:

High drug loading capacity.

Minimal impact on flow properties.

Efficient for lipophilic drugs.

Limitations:

Requires specialized equipment (rotary evaporator).

Solvent selection is critical.

Application: Coevaporation is preferred for high-dose formulations.[14,15].

Comparative Analysis:

Drug Loading Capacity:

Wet granulation > Coevaporation > Geometric mixing

Flow Properties:

Geometric mixing < Wet granulation < Coevaporation

Process Complexity:

Geometric mixing < Coevaporation < Wet granulation

Suitability for Scale-Up:

Coevaporation > Wet granulation > Geometric mixing

Table 1: Comparative Analysis of Geometric Mixing, Wet Granulation and Co-evaporation

Metric	Geometric Mixing	Wet Granulation	Coevaporation
Drug Dissolution	Studies needed to quantify [12, 37]	May improve dissolution depending on binder used [14,39]	Potentially high dissolution due to intimate mixing [15,44]
Flowability	Generally good [11,38]	May require additional processing for good flow [14,41]	Excellent flowability due to spherical particles [15,43]
Production Scalability	Simplest method, easily scalable [11,39]	More complex than geometric mixing, scalability challenges [14,43]	Requires specialized equipment, moderate scalability [15,45]
Cost-Effectiveness	Simplest and potentially cheapest [12,40]	More expensive than geometric mixing due to additional processing [13,42]	Most expensive due to specialized equipment [15,44]

1. **Coating:**

Coat the surface of the powder particles with a hydrophilic material to prevent further absorption of liquid and improve the powder's flow properties.

2. **Compression:**

Compress the powder blend into tablets or compacts using suitable compression equipment [16].

There is a certain variable that needs to be analysed which is Liquid Load Factor

Liquid Load Factor Calculation:

- Determine the maximum amount of liquid drug that can be absorbed by the carrier material while maintaining acceptable flowability and compressibility.
- This is called the "liquid load factor" or "R value" [17,18]

Incorporation of CCD to optimize liquisolid compacts:

Identification of Factors:

Identify the factors that may influence the properties of liquisolid compacts. These can include the type and concentration of liquid vehicle, carrier material, coating agents, and other formulation parameters [20,21].

Selection of Levels:

Decide on the levels of each factor (low, medium, and high) based on the expected range for each variable. This is crucial for designing the experimental matrix.

Experimental Matrix:

Use the CCD to create a matrix of experimental runs. The matrix includes factorial points, axial points, and center points. The number of runs depends on the number of factors and levels chosen.

Preparation of Experiments:

Conduct the experiments according to the combinations specified in the experimental matrix. For each combination, prepare liquisolid compacts using the defined factors and levels [22,23].

Response Variables:

Define response variables related to the performance of liquisolid compacts, such as dissolution rate, drug release, compressibility, or other relevant properties.

Data Analysis:

Analyse the experimental data using statistical tools to determine the main effects and interaction effects of the factors on the response variables. This helps in identifying the optimal formulation.

Optimization:

Use the analysis results to identify the optimal formulation conditions that maximize the desired properties of liquisolid compacts.

Validation:

Validate the optimized formulation through additional experiments to ensure the reliability of the results.

Characterization parameters:

Content Uniformity:

Verify that the distribution of the active pharmaceutical ingredient (API) or other key components is consistent throughout the compact [24]

Dissolution Rate:

Evaluate the dissolution profile of the liquisolid compact to ensure that the drug is released as intended. This is particularly crucial in pharmaceutical applications.

Physical Appearance and Organoleptic Properties:

Examine the overall appearance, color, and physical integrity of the compact. Ensure there are no signs of discoloration, caking, or other defects.

Hardness and Friability:

Measure the hardness of the compact, as it influences its mechanical strength. Additionally, assess friability to determine the tendency of the compact to break or crumble.

Particle Size and Surface Area:

Analyze the particle size distribution and surface area of the solid components in the formulation. This can impact the compact's dissolution and overall performance.

Flow Properties:

Evaluate the flow properties of the liquisolid powder blend. This is important for consistent and uniform tablet or compact formation during manufacturing.

Microscopy:

Examines drug distribution and particle morphology within the LSC matrix. Scanning electron microscopy (SEM) or transmission electron microscopy (TEM)

Moisture Content:

Determine the moisture content of the formulation to assess its stability and potential for degradation over time.

Hygroscopicity:

Evaluate the tendency of the compact to absorb moisture from the environment. Excessive hygroscopicity can affect the stability of the formulation.

In Vitro Drug Release:

Perform in vitro drug release studies to understand how the drug is released under simulated physiological conditions. This is crucial in pharmaceutical applications to predict the formulation's behaviour in the body.

Stability Studies:

Conduct stability studies under different storage conditions to assess the formulation's long-term stability and shelf life.

Compatibility Studies:

Investigate the compatibility of the liquisolid formulation with various excipients, especially in

pharmaceuticals, to ensure no undesirable interactions occur.

X-ray Diffraction (XRD) and Differential Scanning Calorimetry (DSC):

Employ these techniques to investigate the physical state of the drug and excipients, ensuring there are no undesired changes in crystallinity.

Rheological Properties:

Assess the rheological properties of the liquid and powder components to understand their behavior during processing and manufacturing [25].

In vivo studies:

Assessment of pharmacokinetics and bioavailability in animal models.

Recent Advancements: Liquisolid compacts have been a promising area of research in drug delivery, particularly for poorly water-soluble medications. Here's a breakdown of recent advancements in this field:

- **Novel Carrier Materials:** Researchers are exploring new carrier materials beyond the traditional microcrystalline cellulose (MCC) and amorphous cellulose. Silica and its various forms are gaining traction due to their high adsorption capacity, leading to better powder flow in the final product [26-29].
- **Beyond Dissolution Enhancement:** The liquisolid technique isn't limited to just improving drug dissolution. Recent studies show promise in utilizing liquisolid compacts for sustained-release formulations. This allows for controlled drug release over a longer period, which can be beneficial for certain medications [30,31].
- **Variations of the Technique:** New variations of the liquisolid concept are emerging. Liquipellet is a technique derived from the liquisolid approach, involving extrusion and pelletization for better flowability and sustained release [32-34]. Additionally, liquiground combines the advantages of co-grinding with liquisolid to enhance drug solubility
- Mesoporous silicas and clays have been used as efficient carrier and coating materials in liquisolid systems [35,36]

QbD and DoE in Liquisolid Compact Formulation

QbD establishes a scientific framework for pharmaceutical development. It emphasizes understanding the relationship between product and process variables, and designing a process that consistently produces a quality product.

In the context of liquisolid compacts, QbD involves identifying the critical quality attributes (CQAs) of the product, such as drug release, dissolution rate, and tablet hardness. Then, it focuses on identifying the critical process parameters (CPPs) that can influence these CQAs. These CPPs typically include the ratio of drug to carrier material, the type and amount of coating material, and the processing conditions such as mixing time and compression force.

By using QbD, pharmaceutical scientists can develop a design space that defines the acceptable ranges for the CPPs to ensure consistent production of high-quality liquisolid compacts.

How DoE is used in liquisolid compacts

DoE is a collection of statistical techniques for designing experiments, analyzing data, and building models. It is a powerful tool that can be used to optimize the formulation of liquisolid compacts.

In liquisolid compact development, DoE can be used to:

- Identify the most important CPPs that affect the CQAs.
- Investigate the interactions between different CPPs.
- Develop a mathematical model that predicts the CQAs based on the CPPs.
- Optimize the formulation to achieve the desired product characteristics.

There are different types of DoE designs that can be used for liquisolid compact development, such as factorial designs, central composite designs, and Box-Behnken designs. The choice of design depends on the specific objectives of the study.

Benefits of using QbD and DoE in liquisolid compacts

- **Reduced development time and cost:** By using DoE, researchers can identify the most important factors affecting the product quality and optimize the formulation more efficiently.
- **Improved product quality:** QbD ensures a systematic approach to development, leading to a consistent and high-quality product.
- **Regulatory compliance:** QbD is becoming increasingly recognized by regulatory agencies as a valuable approach for pharmaceutical development.

CONCLUSION:

In nutshell we can conclude that liquisolid compacts can bring a paradigm shift in pharmaceutical industry as it has enhanced dissolution and bioavailability, improved stability, controlled release potential. The field continues to evolve, offering exciting possibilities for further enhancing the performance and applications of this innovative technology. The success of liquisolid compacts is evidenced by the comprehensive evaluation process, which encompasses various parameters. This innovative formulation strategy holds particular significance in the pharmaceutical industry, where the bioavailability of poorly water-soluble drugs often poses challenges. By improving drug solubility and dissolution, liquisolid compacts have the potential to enhance therapeutic outcomes and patient compliance. During compression, liquid drug may be squeezed out of a liquisolid tablet, resulting in unsatisfactory hardness. Exploring novel excipients or processing techniques to improve tablet hardness while maintaining drug content. Liquisolid systems require high solubility of the drug in non-volatile liquid vehicles.Developing strategies to overcome solubility limitations, such as using co-solvents or exploring alternative liquid carriers. Liquisolid powder should possess good flowability and compaction properties for large-scale production of capsules or tablets. Optimizing the balance between liquid content, flowability, and compaction properties for industrial-scale manufacturing.Limited invivo studies,Compatiblity and stability are some of the current challenges faced by the liquisolids.However further exploration of techniques and excipients can help in optimizing the dosage form.

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