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SOLUBILITY ENHANCEMENT TECHNOLOGY: LIQUISOLID COMPACT

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ABSTRACT

Poor aqueous solubility remains one of the major challenges in the development of effective oral drug delivery systems, particularly for drugs belonging to Biopharmaceutical Classification System (BCS) Class II and IV. Inadequate solubility often leads to reduced dissolution rate and low bioavailability, ultimately affecting therapeutic efficacy. Among the various approaches developed to overcome this limitation, the liquisolid compact technique has emerged as a simple, cost-effective, and efficient method. The liquisolid compact system involves the transformation of liquid medications or drug solutions into dry, non-adherent, free-flowing, and compressible powder mixtures by blending with suitable carrier and coating materials. This technique enhances drug dissolution by increasing surface area, improving wettability, and enhancing the apparent solubility of the drug.

The present review highlights the fundamental concepts of solubility and its importance in drug absorption, along with an overview of solubility enhancement techniques, with a primary focus on liquisolid compact technology. Additionally, this article discusses the classification, mechanism, formulation components, preparation methods, and evaluation parameters of liquisolid systems. The advantages, limitations, and pharmaceutical applications of this technique are also critically addressed. Overall, liquisolid compact technology offers a promising strategy for improving the dissolution behavior and bioavailability of poorly water-soluble drugs, making it a valuable tool in modern

pharmaceutical formulation development.

KEYWORDS: Liquisolid compact; Solubility enhancement; Dissolution rate; Bioavailability; BCS Class II; BCS Class IV; Non-volatile solvent; Carrier material; Coating material; Drug delivery system.

INTRODUCTION

Solubility is defined as the maximum amount of solute dissolve in the given amount of solvent or the concentration of solute is saturated solution at a certain temperature and pressure. The solubility of drugs is determined by the solvent used and temperature and pressure. The degree of solubility of a drug in a solvent is measured as the saturation concentration. Solvent generally in a liquid form (pure or mixture of two liquids), also in solid and rarely in gases form. The solubility of drug is denoted as parts, percentage, molarity, molality, volume fraction, and mole fraction.[1]

Table 1: Definitions of solubility.[2]

Descriptive terms	Approximate volume of solvent in millilitres per gram of solute
Very soluble	Less than 1
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Slightly soluble	From 100 to 1000
Very slightly soluble	From 1000 to 10,000
Insoluble	More than 10,000

NEED OF SOLUBILITY

After drug administration drug is absorb in GI tract but some factor affects the absorption mostly poor aqueous solubility and poor membrane permeability of the drug. Next step of drug after administration is dissolved in gastric/intestinal or both fluid before permeate the membrane of the GI tract to systemic circulation. Areas of pharmaceutical research which focus on bioavailability of the drug is known as enhancing of solubility and dissolution rate of poorly water- soluble drug.[1]

***Table 2: Biopharmaceutical classification system.*[1]**

BCS class I	High solubility, Low permeability	Propranolol, metoprolol
BCS class II	Low Solubility, High permeability	Ketoprofen, Quetiapine fumarate, Carbazepine
BCS class III	High solubility, Low permeability	Atenolol, ranitidine
BCS class IV	Low Solubility, Low permeability	Hydrochlorothiazide, frusemide

PROCESS OF SOLUBILIZATION

The Process of enhancing the dissolution rate of class Ⅱ and Ⅳ is called solubilisation which include the breaking of interionic or intermolecular bonds in the solute, and formation of new interactions between solute and solvent molecules.[3]

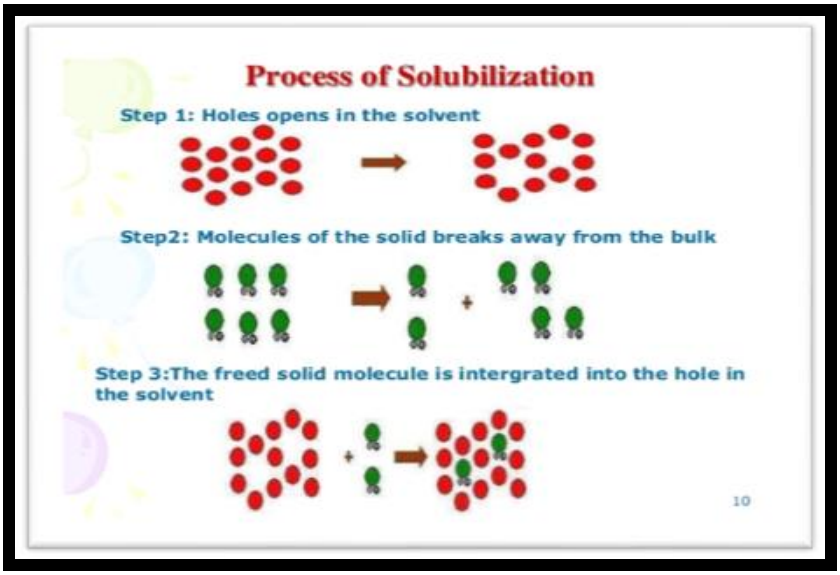

Figure 1: Process of solubilization.[3]

TECHNIQUES OF SOLUBILITY ENHANCEMENT

When solubility of drug is low in aqueous media then different techniques are used to enhance the solubility which are mentioned below.[3]

a) Particle Size Reduction
b) Nanonization
c) Cosolvency
d) Hydrotropy
e) pH Adjustment
f) Sonocrystallization
g) Supercritical Fluid Process
h) Solid Dispersion
I) Inclusion Complexation
j) Self-Emulsifying Systems
k) Liquisolid Methods

LIQUISOLID COMPACT TECHNOLOGY

A major factor in the design of pharmaceutical formulations is solubility of drug. For water insoluble or poorly soluble drugs, dissolution is an important factor for absorption and it is also the rate limiting step. To improve solubility of drugs especially poorly water-soluble drugs (BCS class Ⅱ and Ⅳ), various methods are used such as solid dispersion, inclusion complexes with ß-cyclodextrins, spray drying techniques. Liquisolid compact system is a newly developed technique for improving the solubility and dissolution rate of poorly soluble drugs. In "liquisolid system" (LS), liquid drug forms are converted into powder by transforming a drug into suspension, liquid lipophilic drug or solution of a water insoluble drug in a non -volatile solvent and then blending with specific carrier and coating materials. As a carrier's various grades of cellulose, starch and lactose. And for coating material or covering material very fine silica powder is utilized.[4]

CLASSIFICATION OF LIQUISOLID SYSTEM[5]

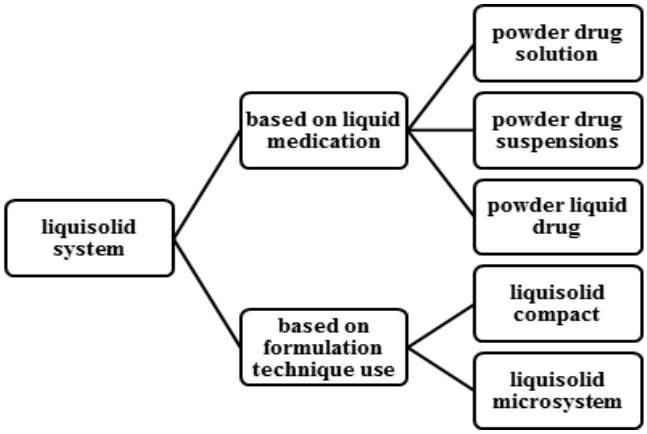

Figure 2: Classification of liquisolid system.[5]

1. Powdered Drug Solutions

When it comes to "powdered drug solutions," it's crucial to highlight that their preparation differs from solvent deposition techniques because it doesn't involve drying or evaporation. In preparation of these solutions, non-volatile solvents are used, and this prevents liquid vehicles from evaporating. Consequently, drug remains within liquid system, which is then dispersed throughout final product. Actual liquid-to-powder percentage ratio that's acceptable can vary and depends on factors such as consistency of powder substrate, quantity of solid drug dispersed in liquid medication, and physicochemical properties of liquid vehicle used. However, acceptable range for liquid-to-powder ratio typically falls between 2% to 52%, with most preferable range being 10% to 35%.

2. Powdered Liquid Drugs

First two, namely "powdered drug solutions" and "powdered drug suspensions," can be created by converting drug solutions or drug suspensions, while latter, "liquisolid systems," is formed by converting liquid drugs into a liquisolid formulation.

3. Liquisolid Compacts

This term refers to tablets or capsules with immediate sustained release characteristics that are categorized under liquisolid systems.

4. Liquisolid Microsystems

Liquisolid compacts are created using previously discussed methods to manufacture tablets or capsules. In contrast, concept of "liquisolid microsystems" is a novel approach that employs a similar technique but introduces an additive, such as Polyvinylpyrrolidone (PVP), into liquid medication. This additive is incorporated into carrier and coating materials to achieve a blend that flows acceptably. This new method offers advantage of producing uniform-sized products when compared to standard liquisolid formulations. Size of liquisolid microsystems can be up to five times smaller than that of liquisolid compacts.

THEORY OF LIQUISOLID SYSTEM[6–8]

Spireas developed the mathematical approach for the calculating the amount of carrier and coating material used in the formulation of liquisolid system because powder can retain only limited amount of liquid while maintaining acceptable flow and compression properties. This method is based on the flowable (Φ-value) and compressible (Ψ-number) liquid retention potential introducing constants for each powder and liquid combination. The Φ-value of powder is defined as maximum amount of a given non-volatile liquid that can be retained inside the bulk [w/w] while maintaining acceptable flowability which is determined by powder flow and measurement of angle of repose. The Ψ- number of a powder is defined as the maximum amount of liquid the powder can retain inside the bulk [w/w] while maintaining acceptable compatibility resulting in a compact of sufficient hardness with no liquid leaking out during compression. The ratio between the weights of carrier (Q) and coating material(q) is:

$$R = \frac{Q}{q} \qquad \text{..... (1)}$$

The weight ratio of the liquid medication and carrier material is known as loading factor (L.f), which can be determined by the below equation.

$$LF = \frac{W}{Q} \qquad \text{..... (2)}$$

The loading factor with concerning to flowability.

$$\Phi LF = \Phi + \varphi \cdot \left(\frac{1}{R}\right) \qquad \text{..... (3)}$$

Where Φ and ψ are the Φ-values of the carrier and coating material respectively.

And with concerning to compressibility:

$$\Psi LF = \Psi + \psi \cdot \left(\frac{1}{R}\right) \qquad \text{..... (4)}$$

Where Ψ and ψ are the Ψ -numbers of carrier and coating materials.

After the calculation of both loading factors of flowability and compressibility of the drug, the appropriate quantities of carrier and coating material need to be calculated to convert the amount of liquid formulation into acceptably flowing and compressible Liquisolid compact system. For this, below equation is used.

$$Q = \frac{W}{Lo} \text{ and } q = \frac{Q}{R} \qquad \text{..... (5 and 6)}$$

Where W is amount of formulation and Lo is loading factor of compressibility and flowability of drug which one is lower.

MECHANISM OF LIQUISOLID SYSTEM[9]

Various mechanisms are used for improve drug release and solubility by the liquisolid compact system. The main mechanism is three, increased surface area, aqueous solubility, and wettability of the drug.

A. Increased drug surface area

If the drug within the liquisolid system totally dissolves in vehicle, which concluded that the powder substrate still in solubilized, molecularly, spread state, so, the surface area of drug available for release is larger than drug particle included in compressed tablets (direct compression).

B. Increased aqueous solubility of drug

Due to the presence of a solid-liquid boundary between liquisolid primary particles and media surrounding, water solubility is increased. The quantity of the vehicle dispersed with drug particle contributes to an increase in the aqueous solubility.

C. Increased wettability

This is fact that the liquid vehicle will either act as surface chemical agent or contain a low surface tension, wetting of the liquisolid particles is increased. This is measured by contact angle and water rising times.

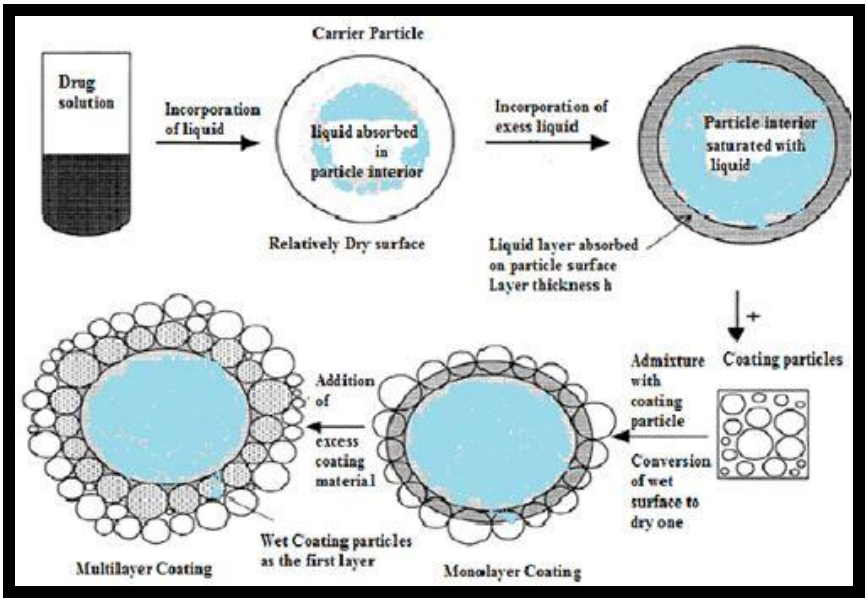

Figure 3: Theoretical model of powdered solution. [9]

FORMULATION OF LIQUISOLID COMPACT[9]

The main components of liquisolid compact are non-volatile solvent, carrier material, coating material and Disintegrant.

1. Drug of criteria

The drug should belong BCS class Ⅱ and Ⅳ. And drug dose and solubility must be low. e.g. naproxen, ketoprofen, Quetiapine fumarate.

2. Non -volatile solvent

The solvent used in formulation must be non-volatile, water-miscible and not highly viscous. It should have good solubilization power and high boiling point for drug used. It acts as a binding agent in the liquisolid formulation. E. g, polyethylene glycol 200,400 and glycerine.

3. Carrier material

It must be porous material possessing absorption properties which contributes in liquid absorption. Both carrier and coating material retain only particular amount of liquid with maintain acceptable flow and compression.

If moisture content of carrier increases, powder flowability will be decreases. e. g, Avicel PH 102, Avicel PH 200.

4. Coating material

Coating material is required to cover the surface and maintain the powder flowability and they must me possess fine and highly adsorptive particles which cover the wet carrier particles and give a dry look to the powder. e. g, silica, aerosol.

5. Disintegrant

It is used to increases the rate of dissolution, water solubility and wettability at liquisolid granules. e. g, sodium starch glycolate and crosspovidone.

PREPARATION OF LIQUISOLID COMPACT[10,11]

1. In first step drug substance is dissolved or suspended in to a selected non-volatile solvent.
2. After that, in prepared solution or suspension carrier material is added to form wet particles.
3. In these wet particles coating material is added for final step to formulate the liquisolid compact.
4. Add disintegrant into final formulation for 10. Compressed by direct compression method.

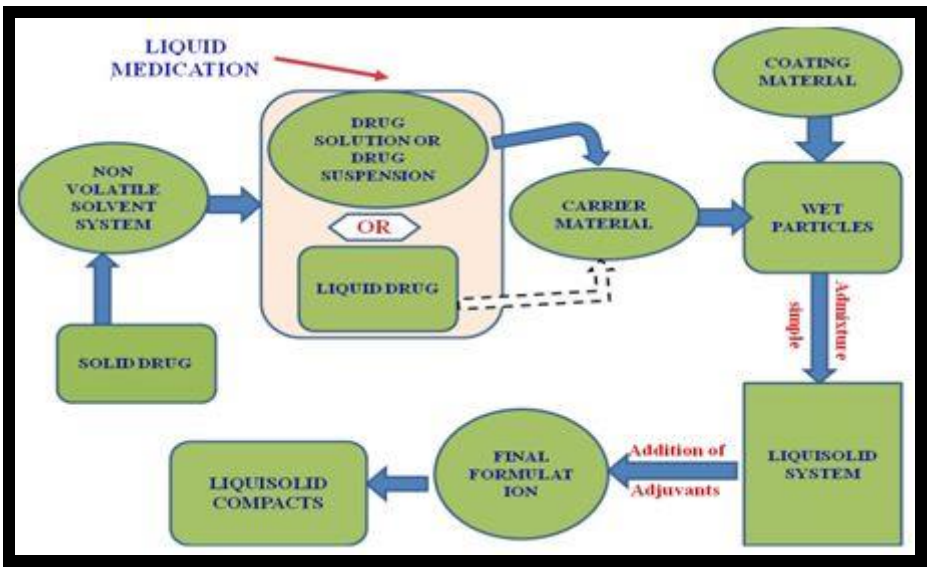

***Figure 4: Preparation of liquisolid compact.*[5]**

EVALUATION OF LIQUISOLID COMPACT[12,13]

The flow properties of the system were determined by angle of repose, carr's index and

Hausner's ratio.

a) **Angle of slide:** The sliding angle assesses how powders behave during flow. Test is conducted using a plate featuring a smooth surface. Powder is positioned at one end, is slowly elevated until the plate turns angular to the horizontal surface, where the powder merely slides. The powder with a 33° angle offers the best flow.

b) Bulk density (B.D)

It is measured by bulk density apparatus. In which weight amount of powder is pour in the graduated cylinder and then measure the volume of powder and calculate by below equation.

$$B.D = \frac{weight\ of\ powder}{volume\ of\ powder}$$

c) Tapped density (T.D)

After the determination of bulk density, the powder contain cylinder tapped for time (usually 100 times) and then measured the volume and calculate the tapped density

$$T.D = \frac{weight\ of\ powder}{tapped\ volume\ of\ powder}$$

d) Carr's index (%)

This is a simplest way for measurement of free flow of powder. Which is calculated by this equation.

$$carr's index = [\frac{(T.D - B.D)}{T.D}] \times 100$$

Where, T.D = tapped density

B.D = bulk density

Value of carr's index is less than15 %, it shows good flow characteristics and if more than 25 %, it's indicating poor flowability.

e) Hausner's ratio

Hausner's ratio is indirect index of powder flow which is calculated by following formula.

$$\text{Hausner's ratio} = \frac{T.D}{B.D}$$

Where, T.D = tapped density

B.D = bulk density

Here, if Hausner's ratio is lower than 1.25 which indicates better flow properties, between

1.25 and 1.5 show moderate flow properties and higher than 1.5 poor flow.

POST COMPRESSION STUDIES[14,15]

1. Weight variation

Twenty tablets are selected from each batch and weighed individually. The average weight and standard deviation are calculated for three batches. If the weight of individual tablets is deviates from the average weight and stander deviation dose not deviate more than 2%, it passes the test. For weight the tablet, electronic weighing balance is used.

2. Thickness

The thickness of tablet is measured from crown to crown by digital micrometre or vernier calliper. Ten tablets are used in this test and variation allowed ±5 % of the size of tablet.

3. Hardness

The hardness of tablets is measured by using Monsanto hardness tester, using 5 tablets. In this the tablet is placed between a fixed and moving jaw and reding indicator set at zero and force is applied till tablet is breaks.

4. Friability

It is measured by using Roche-type friabilator. Six weighed tablets are placed in the friabilator and routed at 25 rpm for 4 minutes. And percentage friability is calculated.

$$frability = \left[\frac{W_0 - W}{W_0}\right] \times 100$$

5. Disintegration test

Six tablets are placed in USP disintegrating apparatus basket, apparatus runs for 10 minutes and then the basket is filtered to observed that tablet is disintegrate or not.

6. In -vitro drug release

Drug release is determined by using a USP type Ⅱ dissolution apparatus. In this method tablet is placed in beaker of apparatus which is already filled with the selected dissolution medium. After every interval of 5 minutes, a 5 ml sample is withdrawn and filtered. Analysed after dissolution using appropriate analytical method. Using stander deviation, concentration is calculated.

7. Differential scanning calorimetry

This test is conducted to identify the thermotropic properties and thermal behaviour of the drug and excipients. disappearance of the characteristic line shows that the formulation of the drug solution in the system.

8. Fourier transform infrared spectroscopy

To estimate the chemical interaction between drug and excipients. If characteristics peaks are present and additional is absent indicates no interaction.

9. X-ray diffraction (XRD) studies

Using an X-Ray diffractometer, XRD tests ascertain the crystalline property of the liquisolid compact mixture. The investigation employs a copper target at a voltage of 40 kV and a current of 30 mA. The device operates at a counting rate of 0.4 s/step and a scanning angle of 5 to 70 °. Evidence of the transformation of pharmaceuticals from crystalline to amorphous forms can be found in the shift in the peak pattern from a clear and crisp pattern to a random pattern.

10. Scanning electron microscopy

This method assists in identifying the surface characteristics of the substance, indicating whether the substance has been crystallized from the liquisolid formulation. The drug's solubilized characteristics in liquisolid system leads to the elimination of these molecular structures.

11. Stability study

Stability study of Liquisolid Compact tablet of Quetiapine Fumarate according to ICH guidelines. The tablet of Quetiapine Fumarate store according to ICH storage condition (30 ± 2 ºC/ 60% ± 5% RH, 40 ± 2 ºC/ 75% ± 5% RH) in stability chamber for 30 days. Average tablet Weight variation, Disintegration, Drug content are analysed for sample.

APPLICATION OF LIQUISOLID COMPACT[16]

1. To enhance drug dissolution

For improve the dissolution rate of low dose insoluble drugs this technique is used. According to research valsartan, ketoprofen, raloxifene hydrochloride are formulated as a liquisolid compacts to improve dissolution rate.

2. To sustain drug release: The liquisolid technique is used in the preparation of sustained release formulations of many drugs in purpose of achieving zero order kinetics. Propranolol is the example of sustain the formulation by this technique.
3. To minimize the influence of pH variation on drug release

In the solubility of weak acids and bases, ionization constant and pH play a major role. The dissolution and bioavailability of the drug are affected by GI fluids, so the liquisolid compact use to improve dissolution rate of drugs.

4. This can be used for insoluble and lipophilic drugs.
5. Improve flowability and compressibility.
6. To control the drug release.

ADVANTAGES[17]

1. Water insoluble solid drugs like BCS Ⅱ & Ⅳ can be formulated into liquisolid system.
2. Enhanced in-vitro and in-vivo drug release.
3. Also modify the drug release by incorporating suitable ingredients.
4. Improve bioavailability of the drug.
5. Controlled release formulation is also possible.
6. Also formulate liquid medication in to liquisolid compact.
7. Production cost is lower than soft gelatine formulations. Industrial production is also possible.
8. Liquisolid system production is similar to conventional tablets.

DISADVANTAGES[18]

1. High dose insoluble drug cannot be formulated in this system.
2. Incorporating more than one carrier to produce free flowing powder leads to increase the weight of tablet, making difficult to swallow.
3. Squeezing out the liquid drug during compression is causes the difficulties in obtaining acceptable compression properties.

CONCLUSION

The liquisolid compact technique has proven to be an effective method for enhancing the solubility and dissolution rate of poorly water-soluble drugs. By improving wettability, surface area, and apparent solubility, this approach significantly enhances drug bioavailability.

The technique is simple, economical, and adaptable to conventional manufacturing processes, making it suitable for large-scale production. Although certain limitations exist, the overall advantages make it a valuable tool in modern pharmaceutical formulation. Future research and optimization may further expand its applications in advanced drug delivery systems.

DISCUSSION

Poor aqueous solubility remains a significant barrier in the successful development of oral pharmaceutical formulations, particularly for drugs classified under Biopharmaceutical Classification System (BCS) Class II and IV. These drugs often exhibit limited dissolution in gastrointestinal fluids, resulting in reduced bioavailability and inconsistent therapeutic outcomes.

The present review critically evaluates various solubility enhancement approaches, with particular emphasis on the liquisolid compact technique. Compared to conventional methods such as particle size reduction, solid dispersion, and inclusion complexation, the liquisolid approach offers distinct advantages in terms of simplicity, cost-effectiveness, and ease of scale-up. The technique involves the transformation of liquid medications into dry, free-flowing, and compressible powders using suitable carrier and coating materials, thereby improving drug dissolution characteristics.

The enhanced performance of liquisolid systems can be attributed to multiple mechanisms, including increased effective surface area, improved wettability, and enhanced apparent solubility of the drug within the formulation matrix. Additionally, formulation variables such as the type of non-volatile solvent, carrier-to-coating ratio, and loading factor play a crucial role in determining the flow properties and release profile of the final dosage form. Proper optimization of these parameters is essential to ensure acceptable flowability, compressibility, and drug release behavior.

Evaluation studies, including pre-compression and post-compression parameters as well as in-vitro dissolution testing, consistently demonstrate improved drug release profiles for liquisolid compacts compared to conventional solid dosage forms. However, certain formulation challenges, such as poor flowability at higher liquid loadings and limitations in handling high-dose drugs, must be carefully considered during development.

Overall, the liquisolid compact technique represents a promising and versatile strategy for

enhancing the solubility and bioavailability of poorly water-soluble drugs. Continued research and optimization may further expand its applicability in advanced drug delivery systems.

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