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Orodispersible Liquisolid Dosage Form: A Recent Pharmaceutical Era of Drug Delivery System

Priya Dipak Jagtap*, Reshma Vijay Jadhav, Ashish Suresh Jain, Bhavesh Dilip Mahajan, Prapti Jagdish Gawand, Prathamesh Vitthal Chaudhari

Shri. D. D. Vispute College of Pharmacy & Research Center, Panvel, India

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Abstract The orodispersible liquisolid system represents an innovative breakthrough in the pharmaceutical field. It combines liquisolid technology with the orodispersible system. In recent years, many drug candidates have been formulated, most of which are lipophilic with poor water solubility. The liquisolid system is ideal for such drugs that exhibit low or no water solubility, possess high permeability (BCS Class II), and necessitate either sustained or immediate release. Powder solution technology, also known as liquisolid formulation, is the process of transforming liquid pharmaceuticals (drugs in solution or suspension) in non-volatile solvents by mixing the solution with suitable carriers and coating agents to create cohesive-free, readily flowable, and compressible powder blends. Orodispersible tablets are becoming more popular as innovative oral drug delivery systems because they can break down into smaller granules or a gel-like form in less than three minutes, making it easier for patients to swallow. Orodispersible tablets provide a fast onset of action due to the inclusion of super disintegrants, which allows for quick absorption through the medication's pre-gastric uptake from the palate, throat, and oesophagus during the swallowing of saliva. This aids in dose reduction. Furthermore, they promote patient compliance and enable proper oral administration for children and elderly individuals who find it challenging to swallow. By using both liquisolid and orodispersible systems, one may improve the dissolution speed, solubility, and bioavailability of medications while achieving a rapid onset of accompanying pharmacodynamic effects. This review study significantly helps readers and researchers understand this novel pharmaceutical dosage form. This article explores the concept and practical use of the orodispersible liquisolid compact method to enhance bioavailability and solubility.

Keywords Orodispersible Tablet, Liquisolid System, Solubility, Bioavailability

1. Introduction

The most popular and extensively utilised medicine delivery technique is oral administration due to its simplicity and ease of usage. However, it can sometimes be inconvenient and inefficient for certain types of drugs. Limited drug absorption brought on by poor solubility, which results in low bioavailability, is one of the main problems with oral medication delivery. The bioavailability of a medication, which is ultimately dictated by the solubility of its active components, affects its therapeutic efficacy [1].

TECHNIQUES FOR SOLUBILITY ENHANCEMENT		
	CHEMICAL MODIFICATION	Change in pH
		Use of buffers
		Derivatization
		Complexation
		Salt formation
	PHYSICAL MODIFICATION	Particle size reduction
		Nano suspension
		Cryogenic technique
		Crystal engineering
	POWDER GRANULATION TECHNOLOGY	Liquisolid conpact
	MISCELLANEOUS METHODS	Supercritical fluid
		Inclusion complex
		Micellar solubilization
		Hydrotropy

Figure 1. Solubility Enhancement Techniques

The number of potential drugs has significantly increased in the past few decades. Nevertheless, the majority of these medications have little water solubility and are extremely lipophilic. Approximately forty percent of new drug candidates face challenges related to solubility and bioavailability, presenting a significant problem for the pharmaceutical industry. Enhancing these drugs' bioavailability and solubility is vital, as the solubility of many drugs directly impacts their bioavailability. Several techniques, as shown in Figure 1, are currently being used to enhance solubility [2, 3].

To address this issue, liquidsolid technology is a cutting-edge and novel technique that turns a liquid medication into an apparently dry, non-sticky, freely-running, and deformable powder [4]. Oily liquid pharmaceuticals and insoluble in water solid medications that are produced as solutions, suspensions, or emulsions in non-volatile liquid carriers can be transformed into powders that are appropriate for tablet compression or capsule filling using the novel "liquisolid" technique. The medication solution in a suitable solvent greatly expands the surface area available for dissolution before the tablets are formed as liquisolids.

Orodispersible tablets were designed to enhance patient compliance. When these formulations come into touch with saliva, they dissolve or break down swiftly, releasing the medication promptly and removing the need for water during delivery. This trait makes them highly suitable for paediatric and geriatric patients. When placed in the mouth, these dosage forms rapidly break down, allowing the medication to dissolve or disperse in saliva. As the saliva travels downward, the medication can be absorbed through the pharynx, oesophagus, and various parts of the gastrointestinal tract. In these cases, bioavailability is considerably greater compared to what is observed with conventional tablet formulations [5].

2. Liquisolid System

Liquisolid technology, a promising, straightforward, and cost-efficient approach to enhancing bioavailability, differentiates itself from more complex methods commonly employed and has garnered considerable research focus in the past decade [6]. The liquisolid system can be categorized as shown in Figure 2 [2].

It is a distinctive “Powder Solution Technology” that enhances adsorption as well as absorption efficiency by combining liquid pharmaceuticals and drug suspensions with appropriate carriers and coating agents, resulting in the formation of easily flowing, dry-appearing, non-sticky, and compressible powder formulations. Enhanced surface area, aqueous solubility, and drug hydrophilicity may all contribute to improved bioavailability. Additionally, the liquisolid approach can be optimized to lower medication dissolution rates, enabling the development of sustained-release systems [7].

Both adsorption and absorption take place when a medication disintegrated in water, a liquid vehicle integrated into a porous-surfaced carrier component with tightly interwoven fibers, like cellulose. Initially, the internal structure of the particles traps the liquid absorbed within them. When this process reaches its saturation point, the liquid is adsorbed onto both the inner and outer surfaces of the porous carrier particles. As a result, a coating material with high specific surface area and strong adsorption properties creates a thin layer on the carrier particle's surface, providing the liquisolid system with the required flow properties [5, 6, 7, 8].

Figure 3 illustrates the process flow.

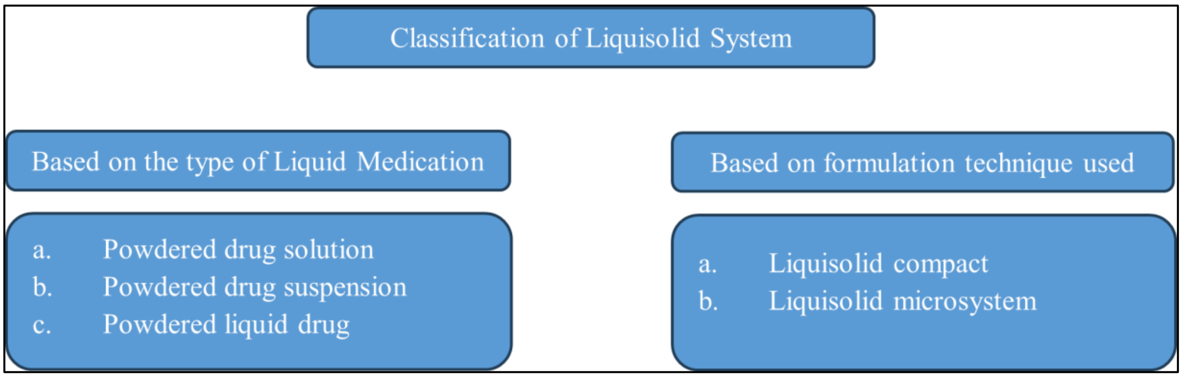

Figure 2. Classification of Liquisolid system

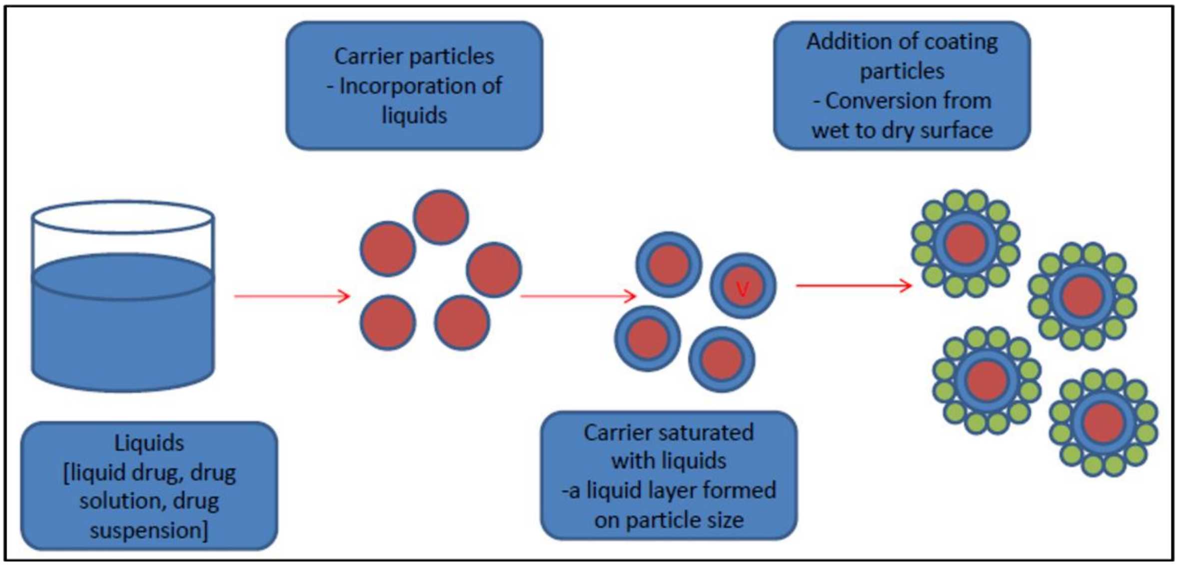

Figure 3. Schematic representation of liquisolid systems

2.1. Components of Liquisolid Systems

Liquisolid compact formulation primarily consists of the following components:

2.1.1. Carrier System

The carrier must have a high liquid absorption capacity and a porous surface. Specific surface area and liquid uptake capacity are two crucial characteristics to consider when formulating the liquisolid system [9]. The powder's flowability decreases when the carrier's moisture content increases, as the coating and carrier materials have a limited capacity to retain liquid while maintaining adequate flow and compression characteristics. Examples of carriers include sorbitol, lactose, starch, and microcrystalline cellulose [10, 11].

2.1.2. Coating Material

A coating material should consist of fine, highly adsorptive particles (with a diameter between 10 nm and 5,000 nm) to cover the moist carrier particles, absorbing excess liquid and giving the powder a dry look. A coating agent is essential to ensure powder flowability and surface coverage [12]. In liquisolid formulations, the most commonly used coating agent is colloidal silicon dioxide (e.g., Aerosil 200, Cab-O-Sil M5). It has been successfully utilized with drugs such as Carvedilol [8], Ritonavir [13], Lovastatin [14], Naproxen [15], Famotidin [16], and Atorvastatin calcium [17].

2.1.3. Non-Volatile Solvents

Liquisolid systems are made with a wide variety of low-viscosity, high-boiling-point, non-volatile solvents that are ideally water soluble, like propylene glycol, glycerin, and polysorbate 20 and 80, as well as PEG 200 and 400. Many studies have shown that solvents are essential in influencing drug release from liquisolid systems. The active ingredient typically exhibits higher solubility in the liquid medium, enhancing drug release. In liquisolid systems intended for modified release, solvents with limited drug dissolution capabilities are used [18]. Additionally, at low concentrations, a liquid vehicle can act as a binder, helping to enhance the compactness of liquisolid tablets. This can be explained by the hydroxyl interactions between the solvents and other excipients in the formulation [4].

2.1.4. Additives

The preparation of liquisolid compacts may require the inclusion of specific additional excipients. For immediate-release formulations, superdisintegrants are the key additives, ensuring the liquisolid compact disintegrates and wets more rapidly. This prevents the drug dissolution process from encountering rate limitation during the disintegration step. In liquisolid formulations, frequently used superdisintegrants include sodium starch glycolate, crospovidone, and croscarmellose sodium.

An interesting excipient that may reduce tablet weight by allowing higher drug loads in the liquisolid system is polyvinylpyrrolidone (PVP) [9]. Additionally, hydroxypropyl methylcellulose (HPMC) is typically employed as a release-delaying substance to extend the duration of medication release from liquisolid tablets [2].

2.2. Mechanism of Liquisolid System

A new formulation-based mathematical model has been created to design liquisolid systems with suitable flowability and compressibility. This model is founded on the powder characteristics referred to as "flowable (ϕ-value) and compressible (Ψ-number) liquid retention potentials" of the constituent powders. According to Spireas' idea, the coating and carrier materials can hold onto some liquid while maintaining sufficient compression and flow characteristics.

2.2.1. Flowable Liquid Retention Potential (Φ-Value)

This refers to the maximum possible quantity of non-volatile liquid (w/w) that a powder can hold while still ensuring adequate flowability. Assessing the Φ-value of both the carrier (Φ CA-value) and coating (Φ CO-value) materials in each formulation is crucial to determining the correct amounts of excipients. This is represented as:

$$\mathrm{Lf} = \frac{W}{Q}$$

Where:

- W represent the weight of the liquid drug.
- Q denote the weight of the carrier material.

2.2.2. The Liquid Load Factor

The liquid load factor (L_f) determines appropriate flowability and is calculated as

$$\mathrm{Lf} = \Phi\mathrm{CA}+\Phi\mathrm{CO}\ (1/R)$$

R denotes the proportion of the weights of carrier (Q) and coating (q) components in the formulation.

$$\mathrm{R}=\frac{Q}{q}$$

As long as the maximum liquid capacity of the carrier material is not exceeded, a well-flowing and compressible liquisolid system can be produced based on the excipient percentage (R) of the powder substrate. The following formulas are used to calculate the necessary amounts of coating (q0) and carrier (Q0) materials required to transform the liquid formulation (W) into a freely flowing, immediately compressible powder [19].

$$Q_0 =\frac{W}{L\circ}\ \text{, and } q_0 = \frac{Q\circ}{R}.$$

2.3. Mechanisms for Improving Solubility and Bioavailability

The main proposed methods for improving solubility and bioavailability include enlarging the drug's surface area for release, boosting its water solubility, and increasing the wettability of drug particles [18].

2.3.1. Increased Effective Surface Area

In a liquisolid system, the drug's available surface area for release is significantly larger compared to that of drug particles in directly compressed tablets. This is due to the fact that the drug in the liquisolid system is entirely dissolved in the liquid vehicle, remaining solubilized and molecularly dispersed within the powder base [9]. As the drug content increases, the solubility limit is raised, which can lead to a reduced release rate. In liquisolid formulations, the release rate is directly proportional to the portion of the drug that is molecularly dispersed (FM). Spireas described FM as the proportion of drug solubility (Sd) to its concentration (Cd) in the liquid carrier [2]:

$$\mathrm{FM}=\mathrm{Sd}/\mathrm{Cd} \text{ Where FM}=1;\ \mathrm{Sd} \geq \mathrm{Cd}$$

2.3.2. Enhanced Medication Solubility in Water

Liquisolid systems are made to increase a medication's solubility, which also enhances the main mechanism of drug release. Although the drug's overall water solubility may not be much increased by the modest amount of liquid carrier in a liquisolid compact, it can enhance solubility at the solid/liquid interface. The liquid vehicle, along with the drug molecules, exits the liquisolid particle, potentially serving as a co-solvent and increasing solubility [5].

2.3.3. Enhanced Wetting Properties

By reducing the tension between the tablet surface and the dissolution media, the non-volatile medium in the liquisolid system helps to moisten the drug particles. This leads to a reduced contact angle compared to standard formulations, thereby increasing wettability [20].

2.4. Advantages

1. It can be used to formulate drugs that are slightly, very poorly, or practically insoluble in water [21].
2. The liquisolid method improves bioavailability [22].
3. This presents a viable substitute for traditional coating methods to improve the photostability of medications in solid dosage forms [9].
4. Adding hydrophobic carriers or retarding agents to liquisolid systems might result in sustained-release formulations [11].

5. Liquisolid tablets or capsules designed for the rapid release of water-immiscible drugs show improved in-vitro and in-vivo drug release in comparison to commercially available products like soft gelatin capsules [20].

2.5. Disadvantages

1. Liquisolid powder formulations demand large amounts of carrier and coating ingredients for adequate flowability and compactibility [2].
2. Not ideal for formulating high-dose insoluble drugs [5].
3. Adding extra carriers to create a free-flowing powder elevates the tablet weight above one gram, making it hard to ingulf [5].
4. Liquisolid systems require the drug to be highly soluble in non-volatile solvents [2].

3. Orodisperible Tablet

The US Food and Drug Administration (FDA) explains orodispersible tablets (ODTs) as “a solid dosage form containing a medicinal substance or active ingredient that disintegrates rapidly, usually within seconds, when placed on the tongue.”

Oral drug delivery is the most commonly chosen method for administering a variety of medications. Recent technological advancements have motivated scientists to produce ODTs that improve patient adherence and ease. ODTs are solid dosage forms that don't require chewing or swallowing since they dissolve or disintegrate quickly in the mouth. These tablets are particularly useful for paediatric and geriatric, who often have difficulties swallowing regular tablets and capsules. The disintegration time of ODTs usually spans from a few seconds to about a minute [22].

Although the compression method is the most widely used for their preparation, other specific procedures include molding, melt granulation, spray-drying, sublimation, freeze-drying, and the effervescent method.

The flavor of these tablets is important as they dissolve directly in the mouth. Various methods have been employed to mask the drug’s bitter taste. Numerous researchers have investigated different drugs in this field. Similar to other solid dosage forms, ODTs are evaluated for hardness, friability, wetting time, dissolution rate, and disintegration time [23].

3.1. Drug Selection Criteria for ODT's

- Capable of saturating the mucous membranes of the mouth.
- Slightly non-ionizing at the pH level of the oral cavity.
- Capable of diffusing and partitioning into the upper gastrointestinal tract (GIT) epithelium.
- Small to intermediate molecular weight.
- Medications in small doses, typically under 50 mg.
- Demonstrate high stability in saliva as well as water.
- Medications with lower bioavailability are well-suited for ODTs.
- Drugs that require frequent dosing are not suitable for ODTs.

3.2. Advantage [5]

1. Avoiding physical blockage during oral administration improves safety by reducing the risk of choking.
2. Improved patient compliance for those individuals with limited access to water, including the disabled, bedridden, travelers, and busy individuals.
3. Well-suited for patients who cannot swallow, including the geriatric, stroke survivors, bedridden individuals, those with renal failure, and those who resist swallowing.
4. Delivers quick drug treatment.
5. Saliva moves through the mouth, pharynx, and oesophagus, leading to enhanced bioavailability and rapid absorption.

3.3. Challenges and Limitations for ODT's

1. Larger doses of drugs, such as antibiotics like ciprofloxacin, can be challenging to manufacture into ODTs, with each adult dose tablet holding approximately 500 mg.
2. ODTs have lower mechanical strength and may disintegrate in the mouth due to their porous or soft molded matrices, making them more fragile and difficult to handle.
3. ODT drugs must be protected from humidity due to their hygroscopic nature. Specific facilities and procedures, including specialized air conditioning systems, can address this issue.
4. Orodispersible tablets need specialized storage and packaging to maintain the product's stability and safety [5].
5. Patients on anticholinergic medications, or those experiencing dry mouth due to reduced saliva production, may not benefit from ODT formulations [24].
6. In addition to having a long half-life, drug candidates should be non-ionizing at the pH of the oral cavity, stable in water and saliva, and able to penetrate the oral mucosal tissue for diffusion and partitioning in the upper GI epithelium (logP > 1, ideally > 2). It is possible to improve the solubility of the active medicinal ingredient by using solid buffers and surfactants [3].

7. Tablets under 7mm are easier to take, whereas those over 8mm are more convenient to handle. Achieving pill sizes that are manageable as well as swallowable can be challenging. Round punches with optimal sizes are used to improve patient compliance and ease of swallowing.

4. Orodisperible Liquisolid Compact

By combining liquisolid technology with the orodispersible system, the phrase "orodispersible liquisolid system" is used. Liquisolid technology has been used to increase the rate at which medications that are not very soluble in water dissolve. Orodispersible pills avoid hepatic metabolism and offer quick action by dissolving in the mouth without the need for water, making them perfect for elderly and paediatric patients.

The drug is mixed with a liquid vehicle and subjected to heating or sonication to achieve complete solubilization. Spireas and Bolton outline 3 steps in the mixing process for incorporating the resulting liquid drug with various excipients in the liquisolid formulation [21].

1. Step One: The liquid medication is placed onto the predetermined amount of carrier material and blended at a rate of one rotation per second for one minute to ensure the liquid medication is evenly distributed throughout the powder.
2. Step Two: The right amount of coating substance is applied and well mixed. To allow the medicine to fully absorb into the interior framework of the carrier and coating components, the resultant powder combination is then evenly distributed across the mortar's surface and left to stand for five minutes [11].
3. Step Three: The disintegrant is added to the powder mixture and thoroughly mixed to form the final liquisolid system.

Figure 4 outlines the entire process flow.

4.1. Methods

4.1.1. Direct Compression

A) A liquid drug can be transformed into a dry liquisolid system without changing its chemical structure. For a water-insoluble drug that is in solid form to be formulated as a liquisolid system, in order to create a solution or suspension with the required concentration, it must first be combined or suspended in a suitable non-volatile solvent. A measured quantity of the prepared drug solution or suspension is then added to a precisely calculated amount of porous carrier material. It should ideally have an enough capacity for absorption. By adding coating material, the resultant wet mixture is turned into a dry, non-adhesive, and readily compressible powder. This phase is particularly effective for excipients with fine, highly adsorptive particles.

To develop orodispersible liquisolid compacts, various additives, including lubricants and superdisintegrants, are incorporated into the final liquisolid solution before compression or encapsulation. Liquisolid tablets are produced by compressing liquisolid powders using the direct compression method. The liquisolid powders are mixed with filler and super disintegrant in a glass mortar for a given time. The mixtures are then lubricated for an additional minute. Finally, a precise amount of each mixture is manually introduced into the die of a tablet press machine to manufacture liquisolid tablets.

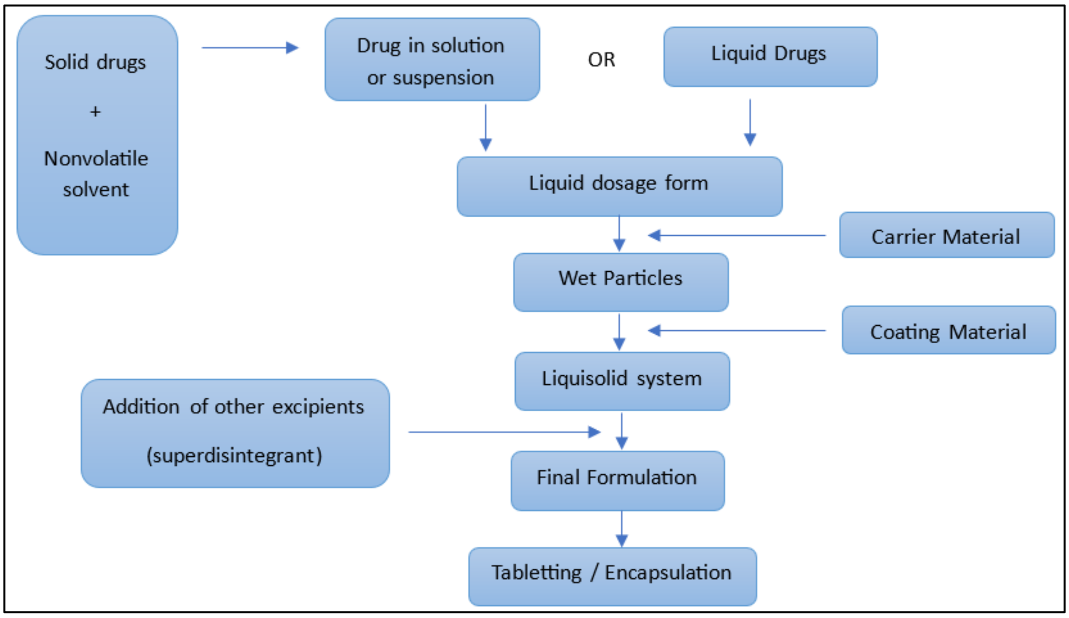

Figure 4. Procedure for preparation of the Orodispersible Liquisolid System

B) Orodispersible liquisolid compacts are formulated by dispersing drugs in dissolution-enhancing agents. A carrier material provides support, while a coating material improves flow properties. Superdisintegrants are incorporated in different ratios, with portions added both within the granules and externally. The granules are formed by passing the moistened bulk powder through a sieve and then drying under controlled conditions. Additional excipients, including glidants and lubricants, are mixed with the granules to optimize flow and compression. Finally, the granules are compressed at a consistent force using a tableting machine to produce tablets with uniform properties.

4.1.2. Granule Formulation from Liquisolid Compacts

The drug is dissolved in a non-volatile liquid vehicle and mixed with a combination of carrier and coating materials in a specified ratio. The mixture is continuously blended in a mortar to ensure uniform distribution. Disintegrants are then incorporated and mixed for a set duration. The prepared liquisolid system is compressed using a die and flat punches. The resulting compact is then crushed and sieved through an appropriate mesh to obtain granules of uniform size.

4.1.3. Granule Preparation Using the Compression Approach

Slugs of a physical powder mixture containing different drugs and polymers are formed by applying compression using a press for a set dwell time. Flat-faced punches of a specific diameter are used, and each slug is subjected to a predetermined compression force. The compressed slugs are then ground using suitable equipment and sieved to produce uniform compacted granules with the drug and polymers. In contrast, the fully compacted formulation’s physical mixture is created by blending the drug and polymer without applying compression [20, 21, 22, 23, 24, 25].

4.2. Pre-Compression Studies of the Orodispersible Liquisolid System

4.2.1. Bulk Density

A bulk density instrument is used to determine the tapped density and loose bulk density. Transferring the mixture into a graduated cylinder allows one to calculate the apparent bulk density. The powder's weight (M) and bulk volume (Vb) are computed.

Formula:

$$Db = M / Vb.$$

Where:

- M denotes the powder's mass.
- Vb signifies the bulk volume of the powder [26].

4.2.2. Tapped Density

For a given amount of time, the mass of the blend in a measuring cylinder is tapped. Next, measurements are made of the blend's weight (M) and minimum volume (Vt). To determine the tapped density, the following formula is utilized:

$$Dt = \frac{M}{Vt}$$

Where:

- M refers to the powder's mass.
- Vt indicates the tapped volume of the powder [26].

4.2.3. Angle of Repose

The sharpest angle created between the surface of the powder pile and the horizontal plane is known as the angle of repose (θ), and it is used to quantify the frictional forces in loose powder. Using the Newman funnel approach, it is ascertained. A determined amount of powder is added to a funnel, which is positioned so that the tip of the funnel just brushes the top of the heap that is building. The following formula is used to determine the angle of repose as the powder freely passes through the funnel:

$$\tan(\theta) = \frac{h}{r}$$

Where:

- θ represents an angle of repose.
- r represents the radius of the cone base.
- h represents the height of the cone [24].

4.2.4. Compressibility (Carr's Index)

Compressibility assesses flowability by comparing powder bulk density (BD) to its tapped density (TD). Carr's index (%) directly measures the strength of the powder's arch and is calculated using the following formula [13]:

$$\text{Compressibility (\%)} = [(TD - BD) \times 100] / TD$$

4.2.5. Hausner's Ratio

Hausner shows that, depending on the amount of friction between its particles, the proportion of tapped density to bulk density may be used to determine how readily a powder flows. Powders with low friction usually have a ratio of around 1.2, while those that are more cohesive and harder to flow have a ratio higher than 1.6. If the ratio is under 1.25, it means the powder flow is good [13].

$$\text{Hausner's ratio} = \text{Tapped density} / \text{Bulk density}$$

4.3. Post-Compression Analysis of the Orodispersible Liquisolid System

4.3.1. Hardness

The force required to shatter a tablet along its diameter is referred to as its hardness. The hardness determines the tablet’s resistance to breaking, chipping, or abrasion during handling and storage. It can be measured using devices such as Monsanto, Erweka, or Pfizer hardness testers [27].

4.3.2. Friability

The Roche Friabilator is used to evaluate friability, which exposes the medicament (tablet) to both abrasion and stress inside a plastic container rotating at 25 revolutions per minute. During each rotation, a pre-weighed sample of tablets is rotated 100 times, in which the tablets are dumped from a height of 6 inches [28]. The following formula is used to calculate the friability:

$$F= [(W_{int.} - W_{fin}) \times 100] / W_{int}$$

Where:

- W_{int} represents the initial weight before friability.
- W_{fin} represents the final weight of tablets after friability.

4.3.3. Wetting Time

Wetting time is a key factor in assessing a dosage form's disintegration properties, as it is directly linked to its contact angle. A quicker wetting time usually means faster disintegration. To determine the wetting time, a tablet is put in a petri plate and water is added. The time it takes for the tablet to become completely soaked is then recorded [29].

4.3.4. Disintegration Test

The disintegration times of fast-dissolving pills must be redefined, as the study requires them to disintegrate without water for accuracy. For this test, 10 mL of water is added to a petri plate with diameter of ten centimeters. The medicament is delicately placed in the middle of the plate, and the amount of time it takes for it to fragment into tiny pieces is noted [30].

4.3.5. Water Absorption Ratio

A sheet of tissue paper is folded twice and positioned in a petri plate with six millilitres of water. The tablet is placed on top of the paper, and the time it takes for the tablet to soak up all the water is recorded. Afterward, the tablet is weighed while it's still wet [24]. The water absorption ratio is then calculated using the formula provided:

$$R = 10 \left(\frac{wa}{wb}\right)$$

Where:

- wa refers to the tablet's weight before it absorbs water.
- wb refers to the tablet's weight after it has absorbed water.

5. Conclusions

The Liquisolid system is recognised as an effective technique for improving the ability to dissolve and dissolution speed of less water-soluble and lipophilic pharmaceuticals. The improvement in the dissolution rate of medicament in liquisolid tablets is most likely due to enhanced wetting characteristics and a greater surface area of the soluble medicament particles. Orodispersible tablets (ODTs) might exhibit a rapid onset of action due to their swift absorption in the oral cavity, pharynx along with oesophagus, thereby bypassing the first-pass metabolism, which contributes to the reduced dose. Compared to conventional tablets, ODTs exhibit rapid disintegration, resulting in better release rates and consequently higher bioavailability. It can be concluded that ODTs can be successfully produced by employing Liquisolid technology and incorporating co-processed superdisintegrants into the formulation helps improve the disintegration and dissolution rates of lipophilic drugs.

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