

INNOVATIONS IN DRUG DELIVERY: LIQUIFIED PELLETS AND RECENT ADVANCEMENTS IN PELLETIZATION TECHNOLOGY***¹Shwetha P.**¹*Assistant Professor, Department of Pharmaceutics, CL Baid Metha College of Pharmacy.

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ABSTRACT

Modern times are seen as a period of improvements in drug delivery methods. Numerous unique strategies, including uniparticulate to multipartite systems, macro to micro and nano particulate systems, are being researched. Pelletization is a revolutionary method of drug delivery that offers a reliable means to administer the medication in a customised pattern. It is beneficial in offering site specific delivery of the drug. These formulations are an effective way to administer medications that have a unpleasant taste, low bioavailability, or a short biological half-life. They are more beneficial than the traditional medication delivery system due to their smaller size.

KEYWORDS: Liquid-mass technology, Pellets, Extrusion spheronisation, Liquid-solid system, Pelletization, Liquid pellets.

INTRODUCTION

The inability of water-insoluble medicines to dissolve poses a significant challenge to formulation scientists. Water insolubility causes formulation issues for approximately half of orally administered drugs. Thus, the pharmaceutical industry's development of new pharmaceutical products is a rate-limiting step toward achieving optimal bioavailability of such drugs.^[1] The physical and chemical characteristics of drugs, such as water solubility and dissolution rate, have a direct impact on bioavailability and, thus, efficacy.^[1]

Because approximately 75% of new drugs are weakly water-soluble, there is great interest in developing techniques to improve drug solubility and dissolution rate.^[2,3] In a simple

approach, the Liqui-Mass technology (also known as Liqui-Pellet technology) has demonstrated encouraging outcomes when it comes to boosting the release rate of water-insoluble drugs.^[4,5] It was created in response to the need to commercialise the concepts of liguosolid technology.^[4] The results of experiments showing improved dissolution rate and manufacturability have both been shown to be extremely promising.^[4]

At this time, the Liqui-Mass technology has been merely used to improve the solubility of medications that are not very water-soluble.^[4] The idea of solubilized API in solid powder admixture seems to have some significant benefits, particularly the drug release kinetics with zero order.

Considering safety, predictability, and the clinical aspect in terms of pharmacokinetics, zero-order release kinetic can be thought of as being very helpful in prolonged release formulation.^[4]

Due to the advantages, it can provide for patients, medical professionals, and pharmaceutical firms, research in the field of prolonged-release formulation is expanding. Compared to ordinary pills, it enables a more sturdy and reliable drug release, improving control over medication plasma level. The sustained-release formulation may also increase patient compliance, lighten the load on medical staff, and perhaps lengthen the patent life of the medicine.

Exploring prolonged-release oral dose formulations employing LiquiMass technology is therefore motivated.^[4-6]

LIQUI-MASS TECHNOLOGY

Liqui-Mass technology, often known as Liqui-Pellet technology, is capable of producing liquid tablets and liquid pellets.^[7,8] Early experiments on the Liqui-Mass or Liqui-Pellet technology have demonstrated encouraging outcomes in terms of the quick release of drugs that are not water soluble.^[7-9]

Despite the fact that Liqui-Mass has only been used to speed up medication release, sustained release is intrinsically compatible with it. The extrusion-spheronization method's gold standard diluent, microcrystalline cellulose (MCC), is well known to be essentially non-disintegrating and appropriate for sustained drug release.^[4] The Liqui-Tablet formulations were created by compacting Liqui-Pellets using a hand-operated tablet press machine under a

predetermined compression force to create a typical convex tablet.^[4]

As long as the API is in a liquid condition, Liqui-Mass technology can be used to create a variety of formulations, including those that incorporate functional excipients or coating techniques. It is a novel and intriguing approach to the future oral dosage form and a great benefit to all of these positive characteristics.^[10,11] When a high-dose formulation is needed, limitations include problems with flow property, compressibility, and unable to function as a dosage form with a manageable size.

The inclusion of liquid medication in dry powder excipients is troublesome in terms of flow property due to the fact that it makes the powder cohesive and interferes with flowability. When considering large-scale production, this poses a serious problem with achieving uniform feed and reproducible filling. To increase the flowability of the formulation, high-dose drugs frequently need more liquid carriers, which in turn require more powder excipients. Nevertheless, as a result of this, the final product would be too large to really employ on patients.

With the development of Liqui-Mass technology, this issue has been resolved, leading to the assumption that Liqui-Pellet and Liqui-Tablet are commercially feasible.^[4] It is reasonable to have a thorough understanding of the ideal extrudate properties for spheronization and the factors influencing how pellets are formed because the goal of this study is to combine liquimass technology concepts with pelletization technology, particularly extrusion-spheronization technology.^[12] It is important to highlight that the liqui-mass system's technology is incredibly adaptable.^[13,14] Wet mass/paste and free-flowing powder, though less frequently, are both included in the liqui-mass system. In theory, the liqui-mass system technology may generate free granule, moldable sheets, liqui-pellet, liqui-tablet, and more.^[13-15]

Additionally, the formulation is very flexible in terms of changes, notably to the liqui-pellet coating. It's intriguing and exciting to learn more about this new liqui-mass technology because of its adaptability. Additionally, this technology has significant benefits like being affordable, primarily utilising green technology, using a straightforward approach, being an easy platform technology to scale up for commercial manufacturing, not requiring an organic volatile solvent, not requiring an advanced technique or machinery, and excipient being widely available and accessible. Other solutions tackling the same problem of enhancing the

bioavailability of low water-soluble medicines may not offer the same benefits.^[13-16]

Despite the significant benefits that the liquisolid technology provides, especially in addressing the limited bioavailability of medications that are weakly water-soluble (i.e., pharmaceuticals in the BCS Class II), there are several serious drawbacks. The inability to create a high dose dosage form with a liquid load factor, poor flowability, poor compatibility, and an inability to construct a high dose dosage form with an appropriate size for swallowing are the main barriers preventing this technology from being economically successful. Hence, while maintaining the advantages of liquid solids, an effort was made to address these problems. As a result, the first of the new generation of oral dose forms, the liqui-pellet, was developed.^[12]

LIQUI-PELLET TECHNOLOGY

Liqui-pellets are a recently created oral dosage form that increases the bioavailability of drugs with low water solubility by accelerating drug release in the gastrointestinal tract.

One of the major issue faced by the pharmaceutical industry is the poor dissolution rate of water insoluble drugs. It is significant to highlight that the biopharmaceutical classification system (BCS) estimates that 40% of drugs in research and 60% of those currently on the market have low water solubility in gastrointestinal fluids.^[12] The term "Liqui-pellet" results from combining the concept of "Liquisolid" idea with "Pelletization Technology."

It differs fundamentally from liquisolid technology in that it does not fall under the domain of liquisolid systems; as a result, rather than being called liquisolid pellet, it is called liqui-pellet. The term "liquisolid formulation" refers to a powdered form of a liquid medication that has been created by transforming powder admixtures that have a dry appearance, are nonadherent, flow freely, and are easily compressible by mixing liquid lipophilic medicines, drug suspensions, or solutions of water-insoluble medications in a suitable non-volatile liquid vehicle.^[12] The name "liqui-pellet" is given to the new dosage form in order to highlight the large amount of liquid that it can hold or the significant liquid load factor that it can support.^[12] This implies that the dosage weight may be reduced, the amount of API in the solubilized state may be increased, or both may be affected by the addition of a considerable amount of liquid medication to the formulation.

The investigation of liqui-pellets using a liquimass system is the main emphasis of this study.

However, it should be highlighted that this unique technology is still in its beginning stage. While considering about the manufacturing at a commercial scale, Liquisolid technology's uncomplicated methodology and affordability are advantageous. The excipients used are quite common and easily available on the market.

In addition to better drug release, the formulation can be altered to create prolonged drug release with a nearly zero-order release kinetic. Despite the advantages, it hasn't yet been able to overcome obstacles, which keeps it from being a widely used product. Major problems include lack of flowability, poor compressibility, and the inability to create big doses of medication without making them too heavy and bulky, which is not optimal for ingesting, are the main causes of this.

The liquisolid blend's flow property is crucial for manufacturing, especially when it comes to tablet or capsule form, as flow property affects uniform feed and repeatable filling. Liquisolid systems, in short, consist of an active ingredient that is dissolved in a liquid carrier to provide a liquid drug. After that, the liquid medication is added to a carrier that has been coated with a nano-sized coating material to provide the mixture of active ingredient and excipients their features of being dry, free-flowing, and easily compressible.^[12] The extrusion-spheronization method can increase flow characteristics, and the advantages of the liquisolid feature can speed up the rate at which medications are delivered.^[12] This new oral dose form is described by the authors as liqui-pellet.

This is done to set it apart from the traditional liquisolid compact, highlight the high liquid load factor that it is capable of, and most importantly make it abundantly clear that it differs fundamentally from liquisolid formulation in such a way that it is not comparable to the liquid-solid system but rather to liqui-mass system. Liqui-pellets outstanding flowability gives you more room to raise the liquid load factor or the volume of the liquid vehicle. Pelletization technology has several built-in benefits, such as a reduced chance of adverse effects from dose dumping, the ability to mix incompatible medications or medications with varied release profiles in the same dose unit, and good flow properties.^[12] The current study focuses on the intrinsic benefits from both liquisolid and pelletization technology.

METHOD OF PREPARATION

Extrusion-spheronization, most frequently employed technique for producing pharmaceutical pellets, is preferred among the several pelletization technologies for creating a Liqui-Pellet.

In brief, extrusion spheronization entails four crucial steps:

- I. dry mixing
- II. the cylinder-shaped transformation of the moist substance in a process called extrusion
- III. A process known as "spheronization" involves shaping and cutting the extrudate into a spheroid using a rotating friction plate with distinctively grooved surfaces.
- IV. drying of the pellet

It should be understood the fact that each of these procedures unique parameters that can alter the physicochemical characteristics of the pellet.^[17,18]

Process of extrusion spheronization

In order to accomplish the granulation and blending of the powder mixture liquid, the process of preparing the material's plastic mass is required. The planetary mixer, high-shear, or sigma blade mixer, etc., being the most popular and straightforward granulators employed. When using the extrusion-spheronization method, the wet granulation procedure is crucial. Wet granulation is made possible using the Twin Screw Extruder (TSE), which may operate constantly. The formed plastic mass is put through the extrusion process, in which a mass of particles is pressed until it emerges through an opening to produce the extrudates.

Depending on the physical characteristics of the materials being extruded, the extrudate length may change. There are five basic types of extruders used for extrusion: screw, sieve and basket, roll, and ram extruders.^[19,20]

Type of extruder	Mechanism	Comment
Screw extruder	Utilises a screw to develop the necessary pressure to force the material to flow through uniform openings	a) Axial: Screen is attached to the screw's head in a perpendicular position to the screw b) Radial: A screen that surrounds the screw discharges the extrudate perpendicular to the screw's axis.
Sieve extruder	An arm that is rotating or oscillating forces the moist substance through a sieve.	From the sieve plate, extrudates descend vertically.
Basket extruder	The sieve or screen, in contrast to sieve extruders, is a part of a vertical cylindrical wall.	Extrudates are formed in horizontal plane.
Roll extruder	They operate by feeding material through a perforated plate or ring die and a roller.	Type1: Inside the cylindrical chamber, a ring revolves around one or more rollers, where each rotates around a fixed axis. Type2: The material is occasionally fed from

		a hopper by a screw into the space between the roller and the die, where the roller or rollers are positioned on the exterior of the ring die. Type 3: A flat, stationary die plate has rollers above it that move around its surface.
Ram extruder	Material is compressed via an aperture using a piston ring that rides inside a cylinder or channel during the forward stroke.	The ram extruder records stronger extrusion forces, and when more water is supplied, less force is required to extrude the wet material via the ram extruder.

Spheronisation

This technique involves uniformly breaking the cylindrically shaped extruded particles into a particular length, which eventually leads to the emergence of spherical shapes. This shaping process occurs as a result of plastic deformation. Extrudates are first cut into lengths that are essentially uniform, the three dimensions of agglomeration shape are identified, and then spheres with a constant diameter are produced. Several stages of the spheronization process, such as a cylinder with rounded edges, dumbbell-shaped particles, elliptical particles, and eventually perfect spheres, can be distinguished depending on how the particles are shaped.^[19-21]

Spheronizer

It is a device composed of a friction plate or horizontal rotating disc that is housed inside a hollow vertical cylinder. Collisions with the rotating disc, other particles, and the wall device cause the extrudates to be applied to the moving plate and break into tiny pieces. The mechanical energy produced by the rotating disc is converted into kinetic energy in the form of a mechanically fluidized bed. While the process continues, the extrudate gradually transforms into a spheroidal structure.

A grooved surface on the revolving disc increases the frictional forces. Based on geometry, there are two distinct sorts of grooves: "cross-hatch geometry," where the grooves are generated from right angles, and "radial geometry," where a radial pattern is used.^[19-22]

FORMULATION COMPONENTS OF LIQUIPELLETS

1) Selection of drug candidate

This method works well with medications that have a low oral bioavailability. To increase bioavailability, drug candidates that fall into BCS classes II/IV must be chosen. E. g. Carbamazepine, Naproxen and Ritonavir, etc.^[23,24] A scientific method for categorizing

active pharmaceutical ingredients (APIs) based on their gastrointestinal permeability and aqueous solubility is the Biopharmaceutical Classification System (BCS).^[25]

2) Choosing a Non-Volatile Solvent

They have low viscosity, a high boiling point, and are inert. In general, the less viscous liquid should be used since it produces free flowing powder with the least amount of carrier and coating agent and reduces tablet weight.

Span, Labrafil, Labrasol, Polysorbate 20/80, Polyethylene Glycol 200/400/600, Propylene Glycol, etc.^[23,26] Water and liquid vehicle (Tween 80) concentrations are two key factors influencing the dissolution rate. It has been discovered that decreasing the water content in naproxen Liqui-Pellet (from 8.62 ml to 4.76 ml, or 1.9 ml/0.95 ml per 20 g of API and excipients) and raising the Tween 80 concentration (from 28% w/w to 32 or 36% w/w) enhance the drug release rate. There is a limit to how much Tween 80 and water can be used, though.^[27]

3) Choosing a carrier material

Carrier material ought to be added to improve compression. These materials have sufficient soaking potential and are porous. As a carrier substance, various forms of cellulose, starch, and lactose are employed.

The capability of the carrier material's absorption and drug inertness should be taken into consideration.^[23-28] The most popular pelletization aid used in the manufacturing of pellets via extrusion-spheronization is microcrystalline cellulose (MCC). When using water as the moistening medium, MCC produces pellets that are very spherical and uniform in size.^[29]

4) Choosing of a coating material

The coating material should have good flow properties and a high adsorptive capacity. Silica of various grades is frequently used for coating. They serve as adsorption behavior's main application, making the material readily flowable.^[23] The substance used as a coating should have tiny, extremely adsorptive particles that help to cover the wet carrier particles and produce the appearance of dry powder by adsorbing any excess liquid.

To cover the surface and keep the powder from sticking, coating material is necessary. An example would be silica (Cab-O-Sil), Aerosil 200, Syloid, 244FP, etc.^[30]

CHARACTERISATION OF PELLETS

Particle size

Standard sieves were used to analyse the particle size of all effective formulations. The digestion process and the stomach's closing mechanism, the pyloric sphincter, are unaffected by smaller pellets (2.4 mm in diameter). The maximum particle diameter for the multiunit formulation should be 1.5 mm.

Since the emptying rate from the feed is highly varied, it becomes difficult to estimate when the pellet size increases.^[31]

Shape of the pellets

Shape of pellets is influenced by geometrical pattern and shape regularity. It will have an impact on the pellet's surface area, particle movement, packing, and compaction properties. It is possible to tell whether a particle has an asymmetrical or spherical shape. The smallest surface area per unit volume is found in spheres. So, it is possible to compare these characteristics between spheres and asymmetric pellets. The ratio of surface to volume can be used to express a pellet's form factor. Shape factor has a minimum value of 6, which corresponds to a sphere.

The pellet is thought to be asymmetrical if the ratio is more than this factor of 6.^[31,32] For a good, uniform distribution, the pellets' shape should be spherical or nearly spherical. Due to faults and cracks during compression, a more atypical spherical shape does not lead to a characteristic release.^[33]

Surface morphology

The surface morphology and cross section of pellets are examined using scanning electron microscopy (SEM).^[31,34,35] The frictional force between the pellets is measured by the angle of repose, which is one of the micromeritic properties of pellets. It calculates the angle between the surface of the pellet pile and the horizontal plane.

It was calculated that the angle of repose would reveal the matrix pellets' flow characteristics. Angle of repose = \tan^{-1} (height of heap of sample/radius of heap of sample)

Mechanical Strength

a) Tensile strength

By calculating the failure load and particle radius, tensile strength is determined.

b) Crushing strength

While the elastic modulus measures the stress required to start plastic deformation, the crushing strength measures the weight necessary to break the pellets.

c) Specific surface area

The amount of obstruction to fluid flow through a plug of compact pellets, such as air, is measured by the surface area of the pellet. A pellet's resistance to flow increases with surface area per gram.^[31-37]

d) Invitro dissolution studies

Particularly in controlled released formulation, in vitro dissolving has been regarded as a crucial component of both medication development and quality assessment.^[31]

CONCLUSION

A simple and economical method of providing sustained-release dosage is Liqui-Mass technology.

In terms of solving the significant shortcomings in liquisolid technology, the newly developed oral dosage form known as liquipellet has demonstrated exceptional achievements. It has never been done in liquisolid technology previously, but Liquipellet can reach increased liquid load factor while preserving outstanding flow properties. Liqui-pellet is expected to be a highly marketable product because it addresses some of the fundamental shortcomings of liquisolid technology.

Further optimization may be possible as flow property may not have to be taken into consideration when choosing excipients and parameters like R-value.

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