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Review Paper

Next-Gen Glycemic Control: An overview of Soft Jelly Matrices to Deliver SGLT-2 Inhibitors

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ABSTRACT

The SGLT-2 inhibitors are especially Empagliflozin which completely changed the way of managing type 2 diabetes and providing the people with good blood-sugar level and strong heart-kidney coverage. Still, even the most common type of one-size-fits-all tablet remains a challenge to many older patients and individuals with swallowing impairments, which implies that they do not always take them accordingly. To address those challenges the present paper analyses the preparation of oral soft jellies that place the patient first to resolve those problems. We explore the science of encapsulating the oily SGLT 2 drugs into hydrocolloid mixes, but this time around the role of natural polymers such as pectin and sodium alginate is employed with current gelling ingredients.We discuss how production is changing to no longer rely on simple molding, to accurate 3D printing (semi-solid extrusion) and now gives us a path to being able to create patient-specific doses. Other than the mechanical ones, we may speak of the hard physical problems of syneresis and hygroscopicity which appear in tropical climates. We also test the reaction of such medicated jellies on a diabetic mouth and indicate that, they may serve as a local buffer of a salivary glucose and help maintain the oral microbiome. Overall this review reveals that soft jelly preparations are not merely a comfort preparation but highly scientific means of increasing the efficacy and psychological adhesiveness of SGLT-2 therapy

INTRODUCTION

Type 2 Diabetes is no longer only a metabolic problem anymore; it is a pandemic health problem, and it is progressively being increasingly complex in the world vastly. The most recent IDF Diabetes Atlas indicates that the patients with diabetes are rapidly rising up the scale, and it is estimated that the figure will rise even further by 2021-2045 [1]. This is not merely a clinical statistic, but is a massive socio-economic blow, particularly in the developing world where the costs of long-term

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treatment are busting the public health budget of countries, and the family pockets of families [9].

Traditionally, the care of diabetes was reduced to the numbers: to lower HbA1c by any means. New diabetes practices suggest that issues of overall health of the person must be considered rather than the blood sugar level, where treatment plan can only be effective when it is realistic and can be adapted to the daily routine of that person.A patient-centered practice goes beyond meeting targets to imply quality life and actual compliance in life [5, 6].

The key new-generation drugs are the SGLT 2 inhibitors such as empagliflozin. These drugs have transformed our way of thinking about diabetes treatment - it is the first-line not only on the level of blood sugar but also protecting the heart and kidneys [10]. However, despite the sophisticated nature of the medicine, the pill form is a thing of the past, which cannot be used by those who require it the most.

One such impediment is that of a so-called pill burden that older adults experience which is quite big and extensive. Since the disease shift is putting increasingly more patients in the 55+ category [2], such issues as dysphagia (difficulty swallowing) are becoming a significant concern [7]. It may physically tire and mentally demoralizing to swallow a handful of hard pills every day, and many people intentionally forget to do so [4].

The lack of alignment between the state-of-the-art drugs and technology that is way back in terms of pill delivery requires transformation. The liquid syrups are simpler to swallow yet face difficulties controlling the correct dosage, might spill and they are not that mobile. This is why creating a soft jelly is logical to do so - it is an intermediate, as it is accurate, and stays in place like a pill, but can be swallowed like a fluid. Convenient to carry jelly would help increase compliance and enhance the results of patients treated with SGLT -2 [8].

2.Pharmacology of Empagliflozin

2.1 Mechanism of Action and Therapeutic Efficacy.

Empagliflozin selectively inhibits glucose reabsorption by the kidney by blocking the SGLT2 transporter in the proximal tubules. The kidneys normally process and recycle nearly all glucose; the drug throws a spanner into the mechanism and so glucose leaks through the urine (glycosuria) [15, 18]. The risk of low-blood-sugar is reduced compared to most other drugs used in diabetes due to its independent action without the help of insulin.

In addition to reducing sugar, empagliflozin possesses good cardiovascular benefits. The EMPA-REG OUTCOME research demonstrated that it is able to reduce the risk of dying because of heart problems and the heart failure. [13, 19]. The additional benefits are attributed to variation in blood flow and metabolism, and thus maintaining the drug at constant blood level is crucial, when changing the form of the drug [20].

2.2 Physicochemical Profile

To prepare a soft jelly using empagliflozin we are forced to address the physical characteristics. The drug is a fine white/yellowish powder with a mol weight of approximately 450.91 g/mol.

A tablet will simply disintegrate in the stomach, but a jelly will need to keep the drug either dissolved or well dispersed throughout the jelly lest it appears in the stomach in lumpy pieces and the dosage levels shift in an uneven manner.

2.3 Implication of Pharmacokinetics and Jelly Matrix application.

Empagliflozin is absorbed (achieving peak blood concentrations (Tmax) approximately 1.5 hours following administration) and has a half-life of approximately 10-12 hours on a single daily dose

with a tablet, thereby making it a pleasant application [11, 17].

A change in the soft jelly makes the new PK dynamics. Provided that the jelly is quickly dissolved in the mouth, some of the drug could be absorbed by the mouth or under the tongue and circumvent first-pass metabolism and potentially bring that Tmax earlier. When the polymer network of the jelly is tight this may even slow down the release rate, which again resembles a tablet, making the levels constant over time [12]. The jelly must be put through a test to ensure that it is equal to that of blood besides being easy to drink.

3.Formulation Soft Jelly Matrices Components.

Once all the forementioned measurements have been completed, the gelling agents that form the skeleton can be developed.

The biggest thing with any oral jelly is, honesty, the matrix itself it consists of, in essence, this three-dimensional net that holds together bits of water and drug in a semi-solid. Choosing the appropriate gelling agent determines the jelly texture almost completely, its properties on chewing and even the contribution of releasing a drug.

- **Natural Polymers**: These are still the most popular with the oral jellies as they are biocompatible and they are quite tasty.
- **Pectin:** Pectin is an extract derived in citrus peel or apple scraps and pectin is becoming popular since it can be used to create stable gels even in acidic environments- very useful in covering bitter drugs [25].
- **Sodium Alginate:** It was collected as brown sea-weed, and cross-linked with Calcium. How it is an ionotronic gelation firming up jellies without heat, which is sweet when using heat-sensitive medications such as Empagliflozin [22, 26].
- **Gelatin:** Traditional melt-in-your-mouth sensation, although its animal derivation may pose an issue to a halal or vegan. Nevertheless, its triangular or three-helix make-up is very clear and flexible [28].
- **Carragennan & Gellan Gum:** You can adjust the snap-to- tough texture into stretchy, and a combination of them can be made to tweak the dissolvability of the matrix [21, 27].
- **Synthetic & Semi- synthetic Polymers:** Due to relatively high variability of natural gum, semi- synthetics such as HPMC or Carbopol are used. They allow you to add viscosity on the dial and stick the jelly a little to the mouth so it can be absorbed effectively [24, 29].

3.2 Sweeteners and Taste masking.

The make or buy of an oral jelly completely depends on taste. Since Empagliflozin is highly bitter, taste masking is something that cannot be neglected. We substitute regular sugar with non-cariogenic polyols in case of diabetic patients. Sweetness and cool buzz come with xylitol and sorbitol, which covers the aftertaste [23]. Besides, they are humectants thus preventing the jelly form shrinking during sitting.

3.3 Solubilizers and Co-solvents : It is not that simple to place a weakly soluble medication such as Empagliflozin into a watery jelly. By merely sprinkling the powder it becomes gritty and bioavailability decreases. This is the reason, why we employ co-solvents such as propylene glycol or PEG 400 or even cyclodextrins, to maintain the drug in a fully dissolved state or evenly dispersed within the gel [30].

3.4 Preservatives and Stabilizers - Jellies consist of 100 percent water, therefore they are a salon to microbes as opposed to tablets. This is why you should have a combination of a good preservative, such as methylparaben and propylparaben, or

sodium benzoate, to preserve the shelf life. You will also require stabilizers to prevent syneresis- when the liquid leaks out of the gel - since that will spoil the drug, and will spoil the user experience [21].

4.Manufacturing Technologies

4.1 Traditional Heating and Congealing Process.

The Heating and Congealing method is the primary method of making oral jellies, which is also referred to as the molding technique. It is simply the same process to produce gummy candies, but with very rigid pharma regulations. It takes two steps to hydrate the polymer and to prepare the sugar or polyol syrup. To begin with, a gelling agent, such as pectin or gelatin, is wetted in water so that it becomes a sol. As that is taking place, you boil a sweet, syrup stuff that hides the bitter flavor of the medication. Then you blend all under smooth stirring. According to Parul and others [34], timing is a crucial factor: you must pour the API immediately before the mixture flows into the molds or it will suffer as a result of heat. Recent optimization is taking the strategy towards Quality by Design (QbD). After evaluating the critical factors, including pouring temperature and cooling rate, Zidan et al. [35] demonstrated that they directly determine the texture and dose uniformity of the jelly. Being too hot may result in a degraded mix, examples include being too cold may prevent the filler from being properly mould, since the mix may be too thick, and taking too long to harden.

4.2 Advanced Production: The Emergency of 3D printing.

Molding is excellent where there are a large number of units, however, it is not that pliable. The reason why 3D printing also known as additive manufacturing is proving to be a game-changer in customized meds is that 3D printing has the capability to produce what are known as Chewable Formulations, on-demand and the exact dosing of the medication depending on the patient [33, 40]. Semi-Solid extrusion (SSE) would be the go-to solution where an overlay of the drugs within a hydrogel is produced to make the final dosage. Boonkaew [39] and Seoane-Viano [38] demonstrate that this allows us to craft complex inside shapes, which bias the release profile, something that molds cannot accomplish.

4.3 Individualization of the Vulnerable Populations.

The magic of 3D printing is actually in producing drugs to adults and children. According to Tagami [31], 3D-printed gummies can be shaped, colored, and flavored to suit kids to be less fearful and increase compliance. Scoutaris [36] went as far as to print medicine on the candy-like stickers, meds mixed with snacks. This technology can enable diabetics to take the so-called Polypills, a single jelly containing various medications. Vithani [37] demonstrated that it is possible to integrate multiple drugs into a single gummy with little cross-leakage. The current case studies on CBD gummies indicate that this is a viable approach to administer fat soluble medicines such as Empagliflozin [32].

5.Parameters of Characterization and Evaluation.

5.1 Organoleptic and Physical Assessment.

In other words, a jelly had to really work, not only its medicine component but also it needed to look good and taste good. People will not stick to the jelly in case it appears sticky or it has a taste of medicine. That is the reason we look at the first to start with its appearance, smell, taste, and even feel

of the mouth. Choudhary et al. [50] indicate that the feel or the feel of breaking the jelly in your mouth is a massive issue when it comes to kids as well as older people, as to whether they will actually consume it or not.

In addition to the above sensory, we determine its physical stability, pH and viscosity. The pH of the jelly must be equal with the oral mucosa (that is approximately, neutral 6.0-7.0) otherwise irritation may occur. Viscosity is assessed using a Brookfield viscometer; this tells us how easy the jelly is to apply and make it maintain its consistency during the manufacturing process [41, 47].

5.2 Bloom Strength and Texture Profile Analysis (TPA).

To not only feel the jelly, a test called Texture Profile Analysis (TPA) is used to give objective figures of hardness, cohesiveness and springiness. Dugar et al. [45] demonstrated that these figures are associated with the ease with which they are swallowed by the patients, particularly those with swallowing problems.

The most important aspect of TPA is that of Bloom Strength that is used to determine the stiffness of the gel. Regarding jellies created using alginate or gelatin, as Roopa and Bhattacharya observe [43], you have to strike the balance on the Bloom strength: too high and you have created something that is rubbery and difficult to swallow; too low and you have created something that is unable to withstand a single dose. Karaman et al. [46] went further to investigate the change of rheology of the gel due to the shear problem but in such a way that when transporting the jelly, it remains solid, but when consuming the product it becomes tender when chewed by your mouth.

5.3 Syneresis: The Issue of Water Loss.

Syneresis - one of the largest pains in jelly making is the syneresis - the falling of the gel and forcing out of the water (the weeping effect). This not only spoils the appearance of the jelly, but also may lead to the proliferation of microbes and disturbance of the dose in the case when the drug gets in that water.

Patel and others [44] had conducted a ton of experiments with the control of syneresis and discovered that it is the concentration of a hydrocolloid that is the primary factor to adjust. Similar problems were observed by Katakam et al. [41] in the case of Glibenclamide jellies, and it was found that increasing the amounts of xanthan gum or sugar in it can actually make the water loss during storage become very slow.

5.4 Uniformity and Kinetics of Drug Release of Content.

It is a necessity to ensure that each of the jellies obtains the precise dose of Empagliflozin. Allen [48] lists all the rigid quality control measures that semi-solid forms require, primarily due to the difficulty of ensuring the even distribution of the drug as compared to the tablets.

Lastly, we examine the in-vitro dissolution profile in order to connect the formulation with what occurs in the body. The mechanism of comparing the results between drugs sticking out of jellies to those of tablets was applied to Mohamed et al. [42], who used standard USP dissolution machines (Type I or II). On top of that they were able to determine the mechanism by which the drug releases into the system (diffusion or erosion) using kinetic models, and Dash et al. [49] provided the math as to how to fit that data into one of zero-order, first-order, or Higuchi models to determine how the drug would behave in-vivo.

6.The Niche That Has Not Yet Been Touched: Oral Health and Salivary Dynamics.

6.1 Diabetic Oral Micro-environment.

Although a lot about the pharmacokinetics of Empagliflozin are familiar to us, there is still very little information as to how an oral jelly will react in the mouth of a real diabetic patient. We must first know that severely hostile environment into which the jelly will penetrate before we can design it. The Type 2 Diabetes patients tend to experience the dry mouth (xerostomia) and low saliva levels (hyposalivation) which definitely confuses the solid tablets dissolution and swallowing process [52, 59].

The mouth of a diabetic is chemically dissimilar. It was observed that saliva glucose is a reflection of blood glucose (Sreebny [51] or Satish et al. [53]). The fact that high glucose in saliva has the ability to reduce the salivary pH and create an inclusive environment in which bacteria and fungi thrive.

6.2 Candidiasis risk and the Oral Microbiome.

Another major concern of any candy-like oral drug is that it may increase gum disease or causes oral thrush especially because diabetics already experience the problem of immunity [56, 60]. Gupta et al. [54] and Pritchard et al. [57] demonstrated that the oral microbiome among diabetics is usually disproportionate, with much more Candida albicans.

It presents a special challenge and opportunity to the jelly design. Adding sucrose would be compensation with the risk of feeding that vicious growth. However, when the non-cariogenic sweetener, such as Xylitol, with antibacterial effects is used so that the jelly might serve as a buffer of saliva and make it neutral, or even alkaline, rather than acidic, upon delivery [55].

7.Dissatisfaction and Future Projections.

7.1 The Hygroscopic dilemma of Critical weather in Tropical climate.

Therefore, though soft jelly matrices are marvelous in making patients take their medicines, they are extremely sensitive to moisture, particularly in such locations as India. According to Bajaj et al. [64], India belongs to the category of climatic Zone IVb, hot and humid and thus the high level of relative humidity does pose a real danger to these hygroscopic formulations. Jellies are essentially hydrophilic networks and unless they are put in a protective state, they will absorb water in the atmosphere, becoming sticky, losing their structure or even becoming covered by bacteria [67].

Bora et al. [63] inform us that is not merely a physical matter, this hygroscopicity; it is a chemical one as well. Additional moisture will accelerate the hydrolysis of moisture sensitive APIs such as Empagliflozin. Lachman et al. [69] further state that the equilibrium moisture content of the jelly in humid regions has to be well adjusted with the environment in order that it does not become a shapeless mass during transportation.

7.2 Strategies of Packaging and Dose Accuracy.

Fighting these environmental stressors therefore requires no ordinary packaging. According to Kaur et al. [66], medicated jellies should have packaging beyond the simple glass jar and move to unit-dose blister packs (such as AluAlu blisters) in developing countries in order to work. This is not just a change of stability, but also a change of safety and the right dose.

Unit-dose containers can be used to ensure that patients do not use the jellies as candy. This is a reinforcement of the pharmaceutical quality of the product, rather than confectionery item by assigning its dose a independent compartment. According to Kommanaboyina & Rhodes [68],

stability is the largest failure mode in distribution and, hence, the stability requires thorough studies in the form of transport simulation before rollout.

7.3 Regulatory Landscape:

It remains a jumble of regulatory status of Medicated Jellies. They are on the border between food supplements and dose forms of pharmaceuticals. Nevertheless, ICH Q1A(R2) requires that you comply with the instructions in order to assert therapeutic efficacy [62]. In India, CDSCO (Central Drugs Standard Control Organization) is becoming more stringent in the case of semi-solid dosage forms. Guidelines of the CDSCO [70] now have it stipulated that manufactures must submit concrete data on in-use stability (i.e. demonstrating that the product remains safe even after the package is opened). Waterman et al. [65] caution, that accelerated aging experiments (predicting shelf-life) may be false with jellies, where physical (such as melting) and chemical (possibly providing a false pass in standard stability tests) changes may occur independently.

CONCLUSION

Truthfully, the addition of Empagliflozin to soft oral jelly matrices is a complete game-changer with the elderly patients. It addresses the most significant pain points the difficulty in swallowing and the burden of the crazy pills head-on. The jellies also enable us to match the doses precisely with non-carietogenic buffering agents, avoiding dysbiosis on the mouth by using technology in 3D printing, like Semi-Solid Extrusion (SSE).

Nevertheless, there remain large gaps: maintaining the formulation in humid, tropical areas (Zone IVb) and sailing through all the narrow regulations of CDSCO and ICH. Those are the obstacles it has to go through and emerge into the market. Concisely, these drugs in jelly form are not merely an easy fall-back option, it is the other way of achieving better patient compliance and the full cardio-renal potential of SGLT-2 inhibitors.

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