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Pharmaceutical Oral Jellies—An Overview

Anitha M, Gowtham R, Harishkumar S, Raksha C R, Vineesh D, Bala Sai Soujith Nidamanuri, Dr Jawahar N*

Department of Pharmaceutics, JSS College of Pharmacy, JSS Academy of Higher Education & Research, Ootacamund, The Nilgiris, Tamil Nadu, India *Corresponding Author; Email: jawahar.n@jssuni.edu.in

Abstract:

Despite significant advances in drug delivery, the oral route remains the preferred method for the administration of therapeutic agents because it has a cheap cost of therapy and is simple to administer, which leads to patient compliance. Oral Medicated Jelly formulation is one type of innovative oral formulation that can be easily absorbed by patients of advanced age, especially those with dysphagia. Oral jelly is also easily chewed and dissolves in saliva; thus, it does not require water. It also has a pleasant texture and look, making it easy to attract and administer to patients. The topic of oral medicated jellies is discussed in depth in this article.

Keywords: Jellies, Semi-solid, Formulation, Evaluation, Oral Administration

INTRODUCTION:

Oral medicinal jellies are palatable solid dose forms that are dissolved in the mouth or pharynx to produce a local or systemic impact. Oral medicated jellies provide a number of advantages over pharmaceutical formulations, but they also have significant drawbacks. Oral medicated jellies can be used as a dosage form for medication delivery via the buccal, labial, gingival, and sublingual routes. They can also contain a variety of medications for the treatment of chronic illnesses. Oral medicated jellies come in a variety of flavors, including mango, pineapple, strawberry, and chocolate, and contain pharmaceuticals for anesthetics, erectile dysfunction, arthritis, hypertension, and sore throat. (1)

The drug delivery mechanism is progressing with gels and jellies. They have a long list of benefits, and fresh alterations are being made in the creation of gels and jellies these days. They exhibit a wide variety of effects and drug delivery with minimal or no systemic toxicity. These are simple ways to administer a medicine topically or systemically. These are quite tasty, and patient compliance is extremely high. They are colorful, appealing, and edible, making it a simple and successful manner of administering medicine to children. Solid dispersion integrated gels, in situ gels, emulgels, and liposomal gels are only a few of the novel types of gels and jellies. Before being commercialized, gels and jellies are tested on a variety of factors. Before they're put on the market, they're put through a series of tests to ensure that they're effective. (2) Zeta potential, syneresis, thixotropy, rheological characteristics, spreadability, droplet size, and ex vivo permeation are some of the evaluation factors. Gels and jellies are semisolid formulations that are translucent or colorful and have a high ratio of gelling ingredients. These systems produce a three-dimensional structure. Gels improve skin permeability, rheological characteristics, stability, and toxicity when used in a unique drug delivery system. As it demonstrates better local activity, the topical drug delivery system is becoming a very essential and very efficient route of drug delivery. (3)

TYPES OF ORAL JELLY:

There are three types of jellies:

- 1 Medicated jelly: These are mostly utilized on mucous membranes and skin for their antibacterial, spermicidal, and local anesthetic effects. There is enough water in these jellies. Jellies provide a local cooling effect after the water evaporates, and a residual coating provides protection.
- 2 Lubricating jelly: Diagnostic equipment such as surgical gloves, cytoscopes, finger stalls, catheters, and rectal thermometers are lubricated with these jellies. Thin, clear, and water-soluble jellies are ideal. Because these jellies are utilized as lubricants for things to be placed into sterile parts of the body, such as the urinary bladder, they must be sterile. (4)
- 3 Miscellaneous jelly:
 - a. Patch testing: These jellies are used to transport allergens that are applied to test sensitivity. When the patches dry, a residual film forms, which helps to keep them distinct and avoids confusing results.
 - b. Electrocardiography: The electrode is coated in jelly to lower the electrical resistance between the patient's skin and the electrode. Sodium Chloride, Pumice Powder, and Glycerine are all present in the jelly. Glycerine acts as humectants in Sodium Chloride, which is a good conductor of electricity. (5)

Advantages:

- 1. Jellies are not only used in medicine but are also used in the cosmetic and food industry.
- 2. It is also used in contact lens formation.
- 3. It has increased the bioavailability and rapid absorption of drugs from the pregastric region, such as the mouth, pharynx and esophagus.
- 4. Oral jellies are the most convenient dosage forms for disabled patients, bedridden patients, travelers, pediatric, psychiatric and geriatric patients, stroke victims, patients with esophageal problems, and people who don't have access to water for the administration of drugs. (6)

- 5. All the medicated jellies have a good mouth feel property.
- 6. Easy administration and easy handling.
- 7. Rapid drug delivery and rapid onset of action.
- 8. No risk of choking or suffocation, thus improving safety.
- 9. Allows high drug loading. (7)
- 10. Manufacturing time is less compared to other conventional dosage forms.
- 11. Orals jellies have good chemical stability.
- 12. Termination of treatment is easier and can be done anytime.
- 13. Easy manufacturing with already available machineries. (8)

Disadvantages:

- 1. Improper formulation of jellies can lead to bad taste.
- 2. Lack of physical resistance in standard blister packs.
- 3. Oral jellies require special packaging for proper stabilization and safety of the stable product. (9)
- 4. Oral jellies are hygroscopic in nature, so they must be kept in a dry place.
- 5. The risk of microbial contamination is high.
- 6. Sterilization of oral jellies is challenging because at high temperatures, they melt easily. (10)

IDEAL CHARACTERISTICS OF JELLY:

- 1. It should dissolve or disintegrate within seconds of administration in the mouth.
- 2. After administration, there must be no residue left in the mouth.
- 3. It should be compatible and have a pleasant feel in the mouth. (11)
- 4. It should be compatible with taste masking.
- 5. It should not be fragile or broken on transportation.
- 6. High drug loading should be feasible. (12)
- 7. It should be stable in altered environmental conditions such as changes in humidity and temperature.
- 8. Production and packaging costs should be economical.
- 9. It should be stable upon storage.
- 10. The excipients used should be inert, safe and compatible with other constituents. (13)

DRUG SELECTION:

- 1. Permeability of the oral mucosa.
- 2. At the pH of the oral cavity, at least partially nonionized.
- 3. Possess the ability to diffuse and partition into the upper GIT epithelium.
- 4. The molecular weight should range from low to moderate. (14)
- 5. Drugs with a low dose, preferably less than 50 mg.
- 6. Drugs with a short half-life or that require frequent dosing are unsuitable for incorporating into jellies. (15)
- 7. The drug should be stable in saliva and water.
- 8. Drugs with a very bitter or unpleasant taste and odour are not recommended for formulating as jellies.
- 9. At the pH of the oral cavity, it should be partially nonionized.
- 10. Ability to diffuse and partition into the upper GIT epithelium (log P >1, preferably >2). (16)

EXCIPIENTS USED IN JELLIES:

- A) Gelling agent: Gelling agents are substances that form a weakly cohesive internal structure when dissolved in a liquid phase as part of a colloidal combination. They are organic hydrocolloids or hydrophilic inorganic substances.
- a. Pectin: Pectin has been utilized as an adsorbent and bulk-forming agent, and it has also been used experimentally in gel formulations for oral sustained drug delivery.
- b. Tragacanth: Tragacanth gum is utilized in a variety of medicinal formulations as an emulsifying and suspending ingredient. It can be found in creams, gels, and emulsions.
- c. Gelatin: Gelatin is commonly utilized in pharmaceutical formulations, particularly as a biodegradable matrix material in implanted delivery systems. Food ingredients and photographic emulsions both include gelatin.
- d. Xantham gum: It is frequently employed as a suspending and stabilizing ingredient in oral and topical medicinal formulations, cosmetics, and food. It's also used to thicken and emulsify liquids. It's also utilized as a hydrocolloid in the food company, and it's a thickening agent in shampoo in cosmetics.
- e. Gellan gum: Gellan gum is an additive used to bind, stabilize, or texturize foods. While naturally occurring, it's also produced commercially via bacterial fermentation.
- f. Sodium alginate: It is found in a range of medicinal preparations, both oral and topical. It is widely employed in the topical formulation as a thickening and suspending agent in a multitude of pastes, creams, and gels, as well as cosmetics and food products.
- g. Carrageenan: It's made from red edible seaweed extracts and consists of linear sulfated polysaccharides. In the food and pharmaceutical industries, they are mostly utilized as a gelling, thickening, and stabilizing agents. Carrageenan is a vegetarian alternative to gelatine used in confectionery. (17)

B) Preservative: A preservative is a natural or synthetic chemical that is added to products such as foods, pharmaceuticals, paints, biological samples, wood, etc., to prevent decomposition by microbial growth or by undesirable chemical changes. Preservatives are substances that are commonly added to various foods and pharmaceutical products in order to prolong their shelf life.

E.g.: Methyl paraben, Propyl paraben, Benzalkonium chloride, Sodium benzoate. (18)

C) Solubilizers: Surfactants, for example, are solubilizer excipients that are added to pharmaceutical formulations to increase the solubility of poorly soluble pharmaceuticals, hence enhancing the bioavailability of the active pharmaceutical component (API).

E.g., Cremophore RH40, PEG 400, Propylene glycol, Sorbitol. (19)

D) Sweeteners: Sweetening agents are the agents which are added to the formulations to mask the bitterness and enhance patient compliance.

- a. Sucrose: Sucrose was the most popular sweetening ingredient because it is soluble in water, cost-effective (the purest form may be obtained for a reasonable price), and physically and chemically stable at various pH levels.
- b. Mannitol: The hydrogenation of fructose produces mannitol, a white, crystalline polyol. It has a sweetness level of around 50% that of sucrose. Because of its negative heat of solution, it is freely soluble in water and provides a slight chilling feeling when chewed or dissolved in the mouth. The smooth consistency and other remarkable features of mannitol make it a favoured excipient in chewable tablet compositions. Because it does not bind water well, it is used as a chewing gum dusting powder. It can be used in confectioneries because it is thermostable.
- c. Sorbitol: Sorbitol is a sugar alcohol and mannitol isomer. It has around 60% of the sweetness of sucrose. It's made from corn syrup or by reducing glucose, which involves replacing the aldehyde group with a hydroxyl group. It's used in cosmetics as a humectant and thickening, as a laxative, in the manufacture of soft gel capsules, and in the treatment of hyperkalemia. Sorb-Tab and crystalline tablet types are commercially available for direct compression.
- d. Saccharin: It's a type of artificial sweetener. It is 250-500 times sweeter than sucrose. It has a harsh or metallic aftertaste, especially at higher concentrations. Saccharin sodium and calcium have great water solubility and stability.
- e. Sucralose: It is a synthetic sweetener. Sucralose is made by substituting three hydroxyl groups in the sucrose molecule with chlorine atoms. It is 320 to 1,000 times sweeter than sucrose, twice sweeter than saccharin, and three times sweeter than aspartame. It has 0 calories since most of the sucralose consumed is not broken down by enzymes. It is thermostable and stable throughout a wide pH range. As a result, it can be used in products with a longer shelf life. When compared to sucrose, the onset of sweetness is slower, but the sweetness lasts longer. (20)

E) Flavouring agents: Flavoring agents are used to provide not only tastes but also a pleasant taste to pharmaceutical preparations such as oral syrup, oral

suspension, elixirs, emulsion, lozenges, chewable tablets, effervescent tablets, dispersible tablets, and jellies. They are utilized to boost patient compliance or make medication dosage forms more appealing.

E.g., Strawberry, Vanilla, Orange. (21)

F) Colouring agents: Colorants, often known as coloring agents, are used to give pharmaceutical dosage forms a distinct appearance.

a) Organic dyes and their lakes :

Dyes:

Dyes are synthetic chemical substances that, when dissolved in a solvent, reveal their coloring power or tinctorial strength8. They are normally 80 to 93 percent pure colorant material (occasionally 94 to 99 percent). E.g.,

Tartrazine, Erythrosine, Sunset Yellow and Patent Blu e V.

Lakes:

Lakes, according to the FDA, are "aluminum salts of FD&C water-soluble dyes stretched on an alumina substratum." Lakes produced by extending the calcium salts of the FD&C dyes are also authorized, but none have been created to date.

E.g.,

Allura

Aluminum lakes- Brilliant Blue Lake, Sunset yellow l ake, Amaranth Lake,

red lake, Indigo

carmine lake, Quinoline yellow lake.

b) Inorganic colors or synthetic colors:
Coal tar is used to make synthetic colors, sometimes known as FD&C colors. The FDA has banned many foods for a variety of reasons, including carcinogenicity, allergy-inducing properties, and overall toxicity. A number of them made children sick. Clinical investigations have indicated that they induce a variety of cancers.

E.g., titanium oxide,

c) Natural colors or vegetable and animal colors: Plants, animals, and microbes provide the natural colors. Because they are non-carcinogenic, non-toxic, and biodegradable, they have been shown to be safe. E.g., Beetroot concentrates, turmeric, cochineal, luetin, saffron. (22)

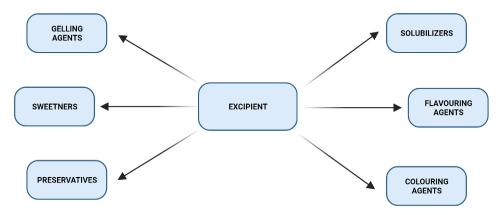


Figure 1: Excipients used in Jellies

METHOD OF PREPARATION:

- 1. All the ingredients are weighed accurately.
- 2. Appropriate quantity of sugar syrup is prepared.
- 3. To the sugar syrup, the gelling agents are added with constant stirring and heated until all the gelling agents are dissolved. (23)
- 4. After the gelling agents are dissolved completely, the stabilizers and solubilizers are added.
- 5. Next, preservatives are added and mixed uniformly.
- 6. The drug is then dissolved in an appropriate solvent and added to the above solution.
- 7. Finally, coloring agents and flavoring agents are added and poured into molds and refrigerated. (24)
- **EVALUATION PARAMETERS:**
- 1. Physical Appearance:
- Clarity, odour, consistency, and texture of the oral jelly were all tested.
- 2. Weight Variation:

The weight of ten jellies was taken after removing them from the molds in a beaker, the average was taken, and weight variation was calculated.

3. Stickiness and Grittiness:

It is evaluated by rubbing the jelly between the two fingers and visually inspecting the stickiness and grittiness. (25)

4. Pourability of the Mixture:

The major virtue of jelly is that it can be easily poured into molds by adding a buffer salt that acts as a retardant, such as trisodium citrate. These retardants often raise the pH of the formulation before adding acid, preventing pre-gelation. Because the retarder concentration is high, the lower the setting temperature and the longer the setting time, the easier it is to set and pour the jelly.

5. pH Determination:

The pH was measured using a digital pH meter after the jelly was dispersed in distilled water (50%) and a 1 percent solution was created. (26)

6. Content Uniformity:

This assessment is carried out for each dosage form to ensure that the content of the medication substance is similar. It is done by crushing and mixing the jelly, then extracting the combination using appropriate media and determining the amount of medication using an analytical method.

7. Viscosity:

The viscosity of the sample is determined using a Brookfield viscometer and a new sample each time. Viscosity in centipoise = Dial reading \times factor (27)

8. Spreadability:

Spreadability is determined by layering the jelly between two glass slides and pressing it flat with a 1000gm weight. Spreadability was calculated as the time it took the two slides to separate.

9. Stability:

Stability studies are carried out in accordance with ICH guidelines and can be assessed by storing the prepared jelly for 90 days at room temperature and analyzing physical appearance changes. (28)

10. Microbial Studies:

These investigations are crucial in understanding the microbiological profile of jellies. Due to the presence of water, jellies are more susceptible to microbial development. The jellies were evaluated for pathogen culture on E. coli, S.aureus, and P.aeruginosa in the specific medium.

11. Percent Drug Content:

Compressing 20 jellies yielded a consistent gel. A quantity of gel equal to 50mg of medication is added, along with enough water, and thoroughly mixed. After sonicating the solution for 45 minutes, make up the volume to 50ml and prepare the filter and dilution. UV spectroscopy is used to determine absorption. (29)

12. Invitro Taste Analysis:

The taste competency of prepared jelly was tested using a 5ml simulated salivary pH. One jelly from each batch is placed in a 50ml beaker with a 5ml solution and filtered for 60 to 120 seconds. Filtrates were tested for drug content using UV. (30)

13. Dissolution Studies:

The invitro dissolving investigation was performed at 50rpm using a USP type 2 paddle apparatus. The dissolving medium was 900ml with a temperature of $37^{\circ}C\pm0.5$. (31)

CATEGORIES OF DRUGS INCORPORATED AS JELLY:

CLASSES OF DRUG	EXAMPLE
Local Anesthetic	Lidocaine
Diurectics	Acetozolamide, Bumetanide,
	Chlorthiazide
Anti-Thyroid Agents	Carbimazole, Propylthiouracil
Anti-Neoplastic Agents	Chlorambucil, Cyclosporin,
	Dacarbazine
Anti-Parkinsonian Agents	Bromocriptinemeslyate,
	Lysuride maleate
Anti-Coagulant Agents	Dicoumarol, Dipyridamole
Anti-Fungal Agents	Butoconazole nitrate,
	Clotrimazole
Anti-Gout Agents	Allopurinol, Probenecide,
	Sulphinpyrazone
Anti-Migraine Agents	Dihydroergtamine mesylate,
	Succinate
Anti-Protozoal Agents	Omidazole, Tindazole,
	Metronidazole
Cardiac Inotropic Agents	Amrinone, Digitoxin,
	Corticosteroids
Anti-Muscarinic Agents	Atropine, Benzhexol HCl,
	Biperiden
Neuromuscular Agents	Pyridostigmine
Nitrates	Isosrbide Dinitrate, Glyceryl
	trinitrate
Anti-Hypertensive Agents	Amlodipine, Dilitazem HCl,
	Carvedilol
Anti-Bacterial Agents	Benethamine Penicillin,
	Clarithromycin
Anti-Histaminic Agents	Cetrizine, Cinnarizine,
	Loratidine
Anti-Emetic Agents	Ondasetron, Domperidone,
	Alizapride
Anti-Helmintic Agents	Mebendazole, Albendazole,
	Thiabendazole
Table No. 1 Drugs incorporated as Jallies	

 Table No. 1 Drugs incorporated as Jellies

CHALLENGES IN FORMULATION:

1. Palatability:

For formulation experts, masking the taste of bittertasting medications chosen for Oral medicated jellies is a challenging challenge. Because most medications are unpleasant, orally disintegrating drug delivery methods frequently include a taste-masking agent. As a result, masking the drug's bitter taste is crucial for patient compliance.

2. Hygroscopicity:

Various oral jelly dosage forms are hygroscopic, which means they lose their physical integrity when exposed to normal temperatures and humidity. As a result, they require humidity protection, which necessitates the use of specialized product packaging.

3. Dose:

The amount of drug that can be included in each unit dose limits the application of technologies utilized for Oral Jellies. Molecules that require large doses provide three key problems to the creation of fast dissolving dosage forms: a) masking the bitter taste of active ingredients, b) mouth feel or grittiness, and c) jelly size. Because most medications require taste masking, the amount of flavor masking materials employed in different dosage forms will depend on the degree of bitterness of the drug in relation to its dose, which will determine the final tablet size. (32)

4. Aqueous solubility:

Water-soluble pharmaceuticals provide a number of formulation issues due to the development of eutectic mixtures, which induce freezing point depression and the formation of a glassy solid, which may collapse upon drying due to the loss of supporting structure during the sublimation process. The use of certain jellyforming excipients like almond gum, which can promote crystallinity and hence add rigidity to the amorphous composite, can occasionally prevent such collapse.

5. Size of jelly:

The ease with which you can take a jelly relies on its size. The easiest size of jelly to swallow is 78mm, whereas the easiest size to handle is one greater than 8 mm, according to research. As a result, finding a jelly size that is both easy to take and easy to handle is tricky. (33)

6. Drug property:

The performance of jellies could be influenced by a variety of physiochemical qualities. For example, a drug's solubility, crystal shape, particle size, and density can all affect final jelly properties like strength and dissolution.

7. Mouth feel:

In the oral cavity, the Oral jellies should not disintegrate into larger particles. The particles produced when the Oral Jellies disintegrate should be as tiny as feasible. After oral dosing, Oral Jellies should leave little to no residue in the mouth. Furthermore, flavorings and cooling ingredients such as menthol increase the tongue feel. 8. Sensitivity to environmental conditions:

Because most of the components used in Oral Jellies are designed to dissolve with a small amount of water, they should be somewhat insensitive to environmental factors such as humidity and temperature. (34)

CONCLUSION:

Oral Medicated Jellies have the potential to outperform other traditional dosage forms in terms of patient compliance, convenience, and time to effect. To conclude, prepared medicinal jelly is more organoleptically acknowledged by patients with disabilities in food and liquid consumption, in other words, those who have trouble masticating and swallowing. The findings of this study suggest that oral medicated jellies may hold great promise for delivering therapeutic dosages to the systemic circulation. These may also have the extra benefit of avoiding hepatic first-pass metabolism. Prepared medicated jelly is inexpensive and widely accepted in the pharmaceutical sector as an innovative, patient-friendly, and handy product.

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