

RECENT ADVANCEMENT IN MEDICATED JELLY: AN UPDATED REVIEWGomeshawari Dewangan*¹, Jhakeshwar Prasad² and Basudha Singh Gautam²¹School of Pharmacy Chouksey Engineering College, Bilaspur - 495004, Chhattisgarh, India.²Shri Shankaracharya College of Pharmaceutical Sciences, Bhilai – 490020, Chhattisgarh, India.***Corresponding Author: Gomeshawari Dewangan**

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Article Received on 19/01/2022

Article Revised on 09/02/2022

Article Accepted on 01/03/2022

ABSTRACT

In the current advancement in drug delivery, oral route remains the convenient and preferred route for the administration of drug to achieve better therapeutic advantages, which leads to patient compliance. Now-a-days, jellies candies are easily accepted by children with full dentition as they enjoy the taste and the chewing property of the jellies because they are often flavoured with fruit juices and extracts. Most of the patient with dysphagia would be choked by water during administration liquid formulation with high viscosity which should be eliminated, thus it has been developed to develop such type of pharmaceutical preparations. Recent development of oral medicated jelly is one of the novel approach, aims to improve safety and efficacy. The formulations can easily be accepted by patient with dysphagia, pediatric and geriatric patients, hence patient compliant dosage form proves beneficial over conventional ones. The aim of this review is to address briefly about its advantages, disadvantages, gelling agents, excipients, method for preparation, evaluation parameters and its significance over conventional form of drugs.

KEYWORDS: Medicated Jelly; Dysphagia; Patient Compliance; Gelling agents; Method of preparation; Evaluation parameters.

INTRODUCTION

Administration via oral route is the most convenient and popular route for various drugs to achieve improved pharmacotherapy advantages because of low cost of therapy and simplicity of administration cause to patient compliance. The recent advances in novel drug delivery systems (NDDS) aims to improve safety and efficacy of dosage form for administration and to achieve better patient compliance and convenience, hence approach leading to development of oral medicated jelly. There are various preparations like tablets, capsules, pills, syrup, emulsion, etc. for oral administration, which are not easily accepted by patient with dysphagia, pediatric and geriatric patients, hence patient compliant dosage form proves beneficial over conventional ones.^[1,2] Development of this type of formulation increase in bioavailability, helps to bypass extensive hepatic first pass metabolism, reduction of dosage wastage, dose dumping, stability and taste masking.

Now-a-days, jellies candies are easily accepted by children with full dentition as they enjoy the taste and the chewing property of the jellies because they are often flavoured with fruit juices, extracts and have sweetness property. Most of the patient with dysphagia would be choked by water while taking liquid formulation with high viscosity which should be eliminated, thus it has been developed to develop such type of pharmaceutical

preparations. Therapeutic response of medicated jellies are most feasible in case of gastro retentive for local treatment of diseases or treatment of systemic conditions.^[3,4]

Jellies

Jellies are translucent, transparent or non-greasy semisolid preparations meant for external and internal applications. Natural gelling agent such as pectin, sodium alginate or from synthetic derivatives of natural substance such as methyl cellulose, and sodium carboxymethyl cellulose for the preparation of jellies.^[5]

Development of oral medicated jelly formulations are more suitable for pediatric, geriatric and patients with dysphagia. The patient with dysphagia should be choked with water during taking liquid formulation, hence this problem should be shortout by administering liquid formulations having high viscosity in the form of jellies.^[6] Jelly formulations have been developed that aim to enhance patient compliance by aiding swallowing.^[7-10] Different gelling agents usually employed are tragacanth, sodium alginate, pectin, starch, gelatin; cellulose derivative such as hydroxypropyl methyl cellulose, methylcellulose, carbomers, polyvinyl pyrrolidone and polyvinyl alcohol using various additives at different concentrations.^[11-13] Commercial oral jelly products of calcium gluconate, metformin hydrochloride,

amlodipine, acyclovir, alendronate, donepezil hydrochloride, sildenafil and tadalafil are available in some countries, but scarcely any products found in those patients who really need them.^[14-16] Medicated jelly is mainly use in the case of local treatment or in systemic condition.^[17,18]

Types of Jelly

Several types of jellies are as follows -

Medicated jelly

These type of jellies contain sufficient water which are mostly used on skin and mucous membrane for their spermicidal, local anaesthetics, and antiseptic properties. It gives a local cooling sensation and applied film gives protection after evaporation of water. For example, ephedrine sulphate jelly is used for vasoconstrictor to prevent the bleeding of nose.

Lubricating jelly

These types of jellies are used for lubrication of diagnostic equipment such as surgical gloves, cystoscopes, catheters, etc.

Miscellaneous jelly

These are meant for different purposes like electrocardiography, patch testing, etc.

Advantages of medicated jelly

- It is can be administer anywhere and anytime without water.

- The treatment can be terminated easily at any time, if required.
- The drugs are released from jelly and swallowed, should be introduced in the gastrointestinal tract either dissolved or suspended in saliva and hence it should be present in a freely bioavailability form.
- It has the potential to overcome the problems of short lived action and variations in drug release and retention times via the oral mucosa.^[19]
- Flexibility in design.
- Improve in patient compliance.
- Reduced dose frequency.
- Medicated jellies are feasible in local treatment of disease of systemic conditions or oral cavity.
- Improve bioavailability or by first pass metabolism.
- Highly acceptable by children, elderly and dysphagic patient.
- Excellent or acute medication.
- Easily manufacturing and lower cost.
- Easily produced, elegant and stable.

Disadvantages of medicated jelly

- It is aqueous preparation hence it needed proper packaging for stabilization and safety of drugs.
- It may produce unpleasant taste in mouth if not formulated properly.
- Due to presence of sorbitol or sucrose in medicated jelly can cause flatulence and diarrhoea.

Table 1: Key Ingredients Used in Preparation of Jelly.

Ingredients	Examples
Gelling Agent	Gellan Gum, Gelatin, Xanthangum, Sodium alginate, Pectin, tragacanth, Carrageneen, MCC.
Stabilizers	Propylene Glycol, Sorbitol, Chelating agent: To prevent the sensitivity of bases EDTA should be used
Preservatives	Methyl Paraben, Chlorhexidine acetate, Propyl Paraben, Benzalkonium Chloride, Sodium Benzoate.

Table 2: Gelling agents use in Formulation.

Gelling agents	Description
Sodium alginate	It is widely used as thickening agent and suspending agent in a various topical and oral pharmaceutical formulations such as pastes, creams and gels, alsoused in cosmetics and food products.
Gelatin	It is used as a biodegradable matrix material in an implantable delivery system. Gelatin is also widely used in food products and photographicemulsions.
Pectin	It is used as an adsorbent and bulk forming agent, experimentally it has been used in gel formulation for oral sustained delivery of drugs.
Tragacanth	In several pharmaceutical formulations, is used as an emulsifying and suspending agent. It is used in creams, gels, and emulsion formulations.
Xanthan gum	It is mostly used in topical and pharmaceutical formulations, cosmetics, and food as suspending agent, stabilizing agent, thickening and emulsifying agent. It is also used as a hydrocolloid in the food in industry, and in cosmetics it hasbeen used as thickening agent in shampoo.
Cellulose derivatives	It is acting as a hydrophilic bulking agent and used to produce thermoplastic polymer. E.g. Methyl cellulose sodium carboxy methyl cellulose.

Challenges in formulating medicated jellies

Palatability

Masking taste of bitter drugs and enhancing taste directly related to patient compliance.^[20]

Hygroscopicity

Some oral jelly dosage forms are hygroscopic and they need protection from humidity so needs specialized product packaging.

Dose /Amount of drug

When the drug possess bitter taste, more excipients should be added to mask taste and this in turn increases the final size of dosage form.

Aqueous solubility

Various excipients in jelly imparts crystallinity and rigidity for water soluble drugs which forms eutectic mixtures.

Size of jelly

The degree of ease in taking a jelly depends on its size. It has been reported that the easiest size of jelly to swallow is 78mm while the easiest size to handle was one larger than 8 mm. Therefore, the jelly size that is both easy to take and easy to handle is difficult to achieve.

The Drug Property

Solubility, crystal morphology, particle size and bulk density of a drug affects the final jelly characteristics.

Mouth feel

Medicated jellies leave minimal or no residue in mouth after oral administration.

Various Components of Medicated Jelly Formulation

I. Gelling Agent

These are hydrocolloids, which form gel like matrix. It dissolve in liquid phase and form weak cohesive internal structure. Examples of gelling agents:

Sodium Alginate

Alginate is obtained from the cell wall of brown algae. Alginates bind with water and forms thick gum. It is used in various oral and topical pharmaceutical formulations. It is generally used as thickening agent and suspending agent in various topical formulations such as pastes, creams and gels.

Pectin

It is a heteropolysaccharide obtained from cell walls of terrestrial plants. It is used against constipation & diarrhoea, where it increases viscosity & volume of stool. Due to its lesser cost it is used in various delivery methods like controlled release, mucoadhesive, gastroretentive, colon- specific drug delivery systems. Also used as stabilizer in cosmetics.

Tragacanth

Tragacanth gum works as an emulsifying and suspending agent in various pharmaceutical preparations such as emulsion, gels, and creams. Also used as thickener, stabilizer, & texturant additive in foods & pharmaceuticals.

Gelatin

Gelatin is generally used as gelling agent in pharmaceutical preparation, vitamin capsules, cosmetic technology, & photographic emulsions. Also used in implantable delivery system to deliver drug suspended in biodegradable matrix.

Xanthan Gum

It is commonly used as a thickening, emulsifying, suspending and stabilizing agents in oral, topical pharmaceutical formulations, cosmetic, and food products. Used as binder in tooth paste & keeps the product uniform. Used as a hydrocolloid in the food preparations & thickening agent in shampoos.

Cellulose derivatives

Used as emulsifier & thickener in food & cosmetic preparations. Also used for relief from constipation problem E.g. Methyl cellulose, Sodium carboxy methyl cellulose.

Agar

Agar-agar is vegetarian product & substitute to gelatine. It is obtained from algae & is white and semitranslucent. It has various applications such as thickener, gelling agent, texturizer, moisturizer, emulsifier, flavour enhancer, and absorbent in pharmaceuticals & food products.

Carrageenans

It is obtained from extracts of red edible seaweeds, & are linear sulfated polysaccharides. They are mainly used as gelling, thickening, and stabilizing agents in food & pharma industry. Carrageenan is vegetarian & is used as substitute for gelatine in confectionery.

II. Sweetners

Sucrose

Sucrose was most preferred sweetening agent because it is soluble in water, it is economical i.e., its highest purified form can be obtained at reasonable price, physically and chemically stable in different pH. It is widely used in combination with sorbitol, glycerin and other polyols to prevent crystallization of sucrose.

Table 3: Different stages of sugar at different temperatures.

Temperature	Stages of sugar
112°	Thread stage
116°	Soft ball stage
120°	Firm ball stage
130°	Hard ball stage
143°	Soft crack stage
154°	Hard crack stage
170°	Caramel stage

Dextrose

They are anhydrous & monohydrate form of dextrose, among them anhydrous form is hygroscopic in nature.

Mannitol

Mannitol is a white, crystalline polyol obtained by hydrogenation of fructose. It imparts a mild cooling sensation when it is chewed or dissolved in the mouth due to its negative heat of solution. It is used dusting powder on chewing gums since does not bind water well. It is thermostable & can be used in confectionaries.

Saccharin

It is an artificial sweetening agent. It is about 250-500 times sweet as sucrose. It has excellent stability, saccharin sodium & calcium has excellent water solubility.

Sucralose

It is an artificial sweetener. It is thermostable and also remains stable in wide pH range. Hence it can be used in products that need a longer shelf life. Compared to sucrose onset of sweetness occurs slowly but sweetness remain for longer duration of time.

Sorbitol

Sorbitol is a sugar alcohol & isomer of mannitol. It is about 60% as sweet as sucrose. It is obtained from corn syrup or by reduction of glucose. It is used as humectant & thickener in cosmetics, used as laxative, formulation of soft gel capsules & in treatment of hyperkalaemia.

III. Colouring agents

Colourants are used for the following reasons:

- To provide aesthetic appearance to dosage forms
 - To increase patient acceptance
 - To maintain colour uniformity of the dosage form.
 - Help in product recognition and differentiation.
- According to the Food drug and cosmetic Act of 1938 Colorants are classified as:

FD & C colours: These are certified colorants that can be used in foods, drugs and cosmetics.

D & C colours: It includes dyes and pigments that is used in drugs & cosmetics which are meant for ingestion & application on mucous membranes.

External D & C: It includes colorants that can be used in external preparations, however its use in products meant for ingestion is not considered as safe due to their oral toxicity.

Types of Colouring agents**Natural Colours**

It is extracted from natural sources or chemically synthesized such as beta-carotene.

Mineral Colours

Example of Mineral colour include mixture of red & yellow ferric oxides gives flesh colour to calamine lotion.

Dyes

These are synthetic chemical compounds that imparts colour when it is dissolved in a solvent such as propylene glycol and glycerine. It contains 80 to 93% pure colorant material.

Lakes

Lakes are aluminium salts of FD&C water soluble dyes extended on a substratum of alumina. Lakes prepared from calcium salts of FD&C dyes are also permitted.

Formulation of Medicated Jellies

Medicated jellies can be prepared by using gelling agents like sodium alginate, gelatin, guar gum, xanthan gum. Citric acid was used as PH modifier. Simple syrup (60%) can be used as a sweetening agent. Methyl paraben (0.18%) and propyl paraben (0.02%) can be used as preservatives. Purified water up to 100% as vehicle can be used. Accurately weighed polymer powders were dispersed in 10ml of purified water maintained at 90°C. The dispersion was stirred using a magnetic stirrer for 20min to facilitate hydration of gelling agents. Add sweetening agent with continuous stirring. Then add citric acid and preservatives with stirring. The final weight was adjusted with purified water, mixed and transferred to moulds and allowed to cool.

Preparation method of Jelly

- All the ingredients will be weighed accurately.
- Drug dissolves in small amount of solvent (ethanol).
- In one beaker sugar syrup should be prepared by adding sugar in beaker.
- Gelling agent will be added to that solution with constant mechanical stirring and heated to dissolve to achieve desired stiffness.
- When completely dissolve of gelling agent, stabilizer and citric acid should be properly added and repeat stirred to enhance softness of the jelly by maintain pH respectively, and then after boil for few minutes.
- Preservative should be added to that polymeric solution after boiling and mixed continuously and uniformly.
- Now, dissolved drugs added before jelly is allowed to set and mix continuously.
- Whole polymeric solution should poured in to moulds and then allowed it for cooling and settling undisturbed by proper enfold the moulds to protect exposure to external environment.



Fig. 1. Some photographs of Jellies Formulations.

Table 4: Review from previous studies of medicated jellies.

S. No.	Drugs	Polymers used	References
1	Ranitidine HCl	Pectin	Carboz et. al., 2017.
2	Ondansetron HCl	Gelatine, Tragacanth, Xanthum gum, Sodium alginate	Jadhav et. al., 2017.
3	Stevioside	HPMC K100, HPMC K15, Sodium metabisulphite	Godbole et al., 2017.
4	Albendazole	Guar gum, Sodium alginate	Anjana et. al., 2017.
5	Glibenclamide	Guar gum, Pectin, Stevia	Nayak et. al., 2016.
6	Levocetizine dihydrochloride	Gellan gum.	Anuradha N. et. al., 2016
7	Clotrimazole	Xanthum gum	Javalgikar et. al., 2016.
8	Albendazole	Pectin, Xanthum gum, Sodium alginate, Gelatine	Tushar V. Ahire et. al., 2016
9	Musa acuminata Colla (AAA Group) peels	-	Noor Azwani Mohd Rasidek et. al., 2016.
10	Palonosteron HCl	Sodium alginate, Carbopol 940, Tragacanth gum, Gelatine, Xanthum gum, Carrageenan	Dubey et. al. 2015.
11	Ketoconazole	Xanthum Gum, Sodium carboxy methyl cellulose	Rao et. al., 2015.
12	Guava peels (Psidium guajava)	Pectin	Pereira et. al., 2015.
13	Carbamazepine	Pectin, Guar gum, Gellan gum	Prakash et. al., 2014.
14	Tadalafil	Carbapol 940	Natarajan et. al., 2014.
15	Curcumin	Pectin	Swapnil et. al., 2014.
16	Ofloxacin and Ornidazole	Xanthum gum, Carrageenan	Salunke et. al., 2013.
17	Calcium supplement	Pectin, Gelatine, Agar, Tragacanth gum, Sodium alginate	Mahavir Chajed et. al., 2012.
18	Glimipiride	Guar gum	Shirse et. al., 2012.
19	Ajowan extract	Sodium alginate, Tragacanth	Deborah et. al., 2010.
20	Fruit wastes containing Citric acid	Coca pod husk, Pectin	Apsara et. al., 2002

Evaluation Parameters

Physical appearance

Physical examinations are important regarding patient compliance and acceptance. The prepared jellies were examined visually for color, texture, clarity and consistency.

Stickiness and grittiness

Stickiness and grittiness should be examined by visual inspections of the formulations by slowly rubbing the

jelly sample by two fingers.

pH

The pH of the jellies were examined using digital pH meter at room temperature. For this, 0.5 g of jelly should mixed in 50 ml of distilled water to make 1% solution and the pH was noted. The pH of the final jelly have influence on not only stability but also on the taste.^[21]

Pourability of the mixture

The jelly formulation mixture should be easily pourable in the moulds. The buffer salts (retarders) like trisodium citrate play an important role in this process, which approaching of the pectin molecules during the hot phase is interfered sterically and also raise the pH-value before the acid addition, thus preventing pre-gelation. The higher the buffer salt, i.e. retarder, concentration, the lower the setting temperature and the longer the setting time which provides sufficient time for pouring and setting of the jelly.^[22]

Taste evaluation

Taste evaluation was done by the volunteers. Five grams of optimized formulation should kept at taste panel experts and for 5 seconds have told to place the gel in their mouth. They were asked to comment on the taste.^[23]

Viscosity study

Viscosity of jelly was carried out using Fungilab viscometer in which the system is non-newtonian spindle no. 4 should be used. It was measured for fixed time 2 min at 1.5 rpm at $25^{\circ}\text{C} \pm 5^{\circ}\text{C}$.

Texture analysis

In this technique, pressing the gel surface with two finger. A 12 mm diameter hemispherical probe was used to replicate the geometry of a finger pressed into the sample. The travelling probe is directly connected to a load cell which measures sample response as a function of probe penetration.

Content uniformity

At first, jelly from the each formulation were taken, crushed and mixed. Drug equivalent of mixture was extracted by suitable media from the mixture. The absorbance of each solution should measure by UV-visible spectrophotometer at suitable wavelength or the quantity of drug contain in each extract was examined using suitable analytical method. This test is to ensure that each dosage forms contains equal amount of drug substances i.e. active pharmaceutical ingredients within the batch.

In-vitro dissolution study

The USP paddle type apparatus used for in-vitro dissolution study by using dissolution medium (900ml) was kept at $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ and 50 rpm. 5 ml of sample should withdrawn and diluted up to 10 ml in volumetric flask with same and 5 ml sample withdrawn after 10, 20, 30, 40, 50, 60, 90, and 120 min and sink condition is maintained by replacing with fresh media. The sample were determined for the drug content using UV-spectrophotometer or by suitable analytical method. Then % drug release was calculated after absorbance was taken.

Spreadability

Jelly (2.5 g) was placed between 2 glassslide and compressed to proper thickness by keeping 1000 gm

weight for 5 minutes for the determination of spreadability. The time in second needed to separate 2 slides were taken for the measure of spreadability. Less time interval to cover the distance of 7.5 cm shown better spreadability.

$$S = W \times L/T$$

Where, S = spreadability, W = weight tide to upper slide, L= length of glass slide (7.5cm), T= time required to separate 2 slides.

Syneresis

It is the separation of water from the gel and contraction of the gel upon storage. If limited concentration of gelling agent should employed then it is more prominent in the gels. All the jellies were observed for signs of syneresis at room temp ($25^{\circ}\text{C} \pm 5^{\circ}\text{C}$) and $8^{\circ}\text{C} \pm 1^{\circ}\text{C}$. The formulations showing signs of syneresis were refused and not selected for further studies.^[24]

Stability Studies

This study should be reported as per ICH guidelines, the samples should be placed at various temperature ($0-8^{\circ}\text{C}$) and at room temperature for 3 months. The sample of jelly should observed for viscosity, appearance and pH at interval of 1 month. All the measurements were performed after allowing the samples to be equilibrated at 25°C for 2hr.

Limitations of pharmaceutical jellies

- Cost-intensive production process.
- Jellies requires special packaging for properly stabilization & safety of stable product. It is also shows the fragile, effervescence granules property.
- Higher concentration of drug cannot be incorporated.

Applications of medicated jelly

- Paediatric and geriatric patients who have difficulty in swallowing or chewing solid dosage forms.
- Patients having risk of choking.
- Geriatrics who cannot swallow a daily dose of antidepressant.
- An eight-year old with allergies who desires a more convenient dosage form than antihistamine syrup.
- A patient who has no access to water for consuming dosage form.

CONCLUSION

From this review, it may concluded that the recent development of medicated jellies formulations can easily accepted by patient with dysphagia, pediatric and geriatric patients, hence patient compliant dosage form proves beneficial over conventional ones. The formulation is one of the novel approach, aims to improve safety and efficacy. For the preparation of formulations, several gelling agents and excipients are to be used and sugar syrup should be used as sweetness or improvement in the acceptable taste, which are mostly accepted by children in current period as jelly candies.

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