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ORAL MEDICATED JELLIES AS A EMERGING PLATFORM FOR ORAL DRUG DELIVERY IN PEDIATRICS

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ABSTRACT

Oral route is the convenient and acceptable route for better patient compliance and easy administration. Oral medicated jellies remain popular among the consumer and children and hence it has continued commercial production. It is an attractive and palatable dosage forms for pediatrics and can be administered without water in the oral cavity meant to be dissolved in mouth or pharynx for its local or systemic effects. These dosage form can be adopted for delivery of drug across buccal route, gingival route, labile route and sublingual route. It has estimated that about 50% of population has problem of swallowing tablets especially pediatrics and geriatrics. Jellies are the most preferred dosage form for even dysphagia patients. Jellies are formulated by Heating and congealing technique. Jellies are semisolid dosage form as they are transparent, non-greasy and can be used internally as well as externally. For any pediatric formulation color, taste, flavor, texture and its acceptance is very important. It serves as a novel dosage form with wide application in pharmaceuticals, nutraceuticals and over the counter medicines. Jellies are evaluated for further evaluations such as weight variation, spreadability, content uniformity, syneresis, palatability, dissolution etc.

KEYWORDS: Soft chew, oral medicated jelly, taste masking, gelling agent, dysphagia, pediatric formulation.

INTRODUCTION

Patients are usually comfortable with oral drug delivery system since it is non-invasive and usually offers low cost of treatment. Most of the pediatric formulation have many drawbacks.

The main evident drawback of the oral solid dosage forms like tablets, capsules is difficulty in swallowing especially for pediatrics, geriatrics and other population suffering from nausea and vomiting leading to patient's incompliance, but it also applies to people who are ill in bed and to those active working patients who are busy or travelling, especially those who have no access to water.

According to the 17th edition of Japanese Pharmacopoeia jellies are non-flow able gelatinous preparations of definite size and shape, meant for oral administration. "Jelly can be defined as transparent or translucent non-greasy, semisolid preparations meant for external as well as internal application". Drugs which have rapid onset of action, whose main absorption site is stomach and small intestine can be formulated as jelly. Medicated jellies are able to release drug in the mouth and for absorption passed through local oromucosal tissues and through pre-gastric, gastric and post gastric segments of the gastrointestinal tract.

Now-a-days, jelly candies have become very common in children as they enjoy chewing the jelly and it may use as a preferable method for drug administration as it is alternative to solid and liquid dosage form. Medicated jelly can be used in local treatment of ailment related to oral cavity & also in the treatment of systemic condition. Drugs with unpleasant taste like erythromycin, acetaminophen, aspirin, ibuprofen & antacids, minerals & vitamin supplements can be formulated as soft chewable dosage form.

The sources from which jellies can be prepared are natural gums like tragacanth, pectin, sodium alginates or from synthetic derivatives like methyl cellulose and sodium carboxy methyl cellulose. By using pharmaceutical jellies as dosage form, drug is delivered through sublingual route, buccal route, labial route and gingival route. Jellies can be used as a choice for psychiatric and patients suffering from stroke, nausea, thyroid disorder, Parkinson's diseases & multiple sclerosis, vomiting and motion sickness. Oral medicated jellies disintegrate rapidly in saliva, usually in a matter of seconds, without the need of water. Common among all age groups, dysphasia is observed in about 35% of the general population, as well as up to 60% of the elderly institutionalized population and 18-22% of all patients in long-term care facilities. In the world market, US is the forerunner with a shares of 20% in medicated jelly formulations. Medicated jelly can provide rapid buccal absorption of drug or the drug may be introduced in GIT is dissolved or suspended in salivary fluid thereby providing rapid therapeutic action.

Dysphagia

Dysphagia refers to a patient's perception of difficulty in the passage of a swallowed bolus from mouth to stomach. Patients typically describe this as a sensation of food "sticking" in the throat or chest. It is also called as "choking" to describe the same feeling. Swallowing disorders can present with a variety of symptoms other than dysphagia. The most common symptoms are swallow-related coughing and regurgitation of previously swallowed food or liquid. Disorders of swallowing may result from problems with neural control, muscular coordination, inflammation or neoplasia.

Oral mucosa

It is a term used to relate the soft tissue lining of the oral cavity and it includes the – Mucosa, Epithelium, Lamina propria, Submucosa. The total area of the oral cavity is about 100 cm^2, the oral mucosal surface is constantly washed by the saliva (daily turn is about 0.5-2L).The salivary pH ranges from 5.6 to 7.9 and it depends upon the flow rate.

Structure of oral mucosa

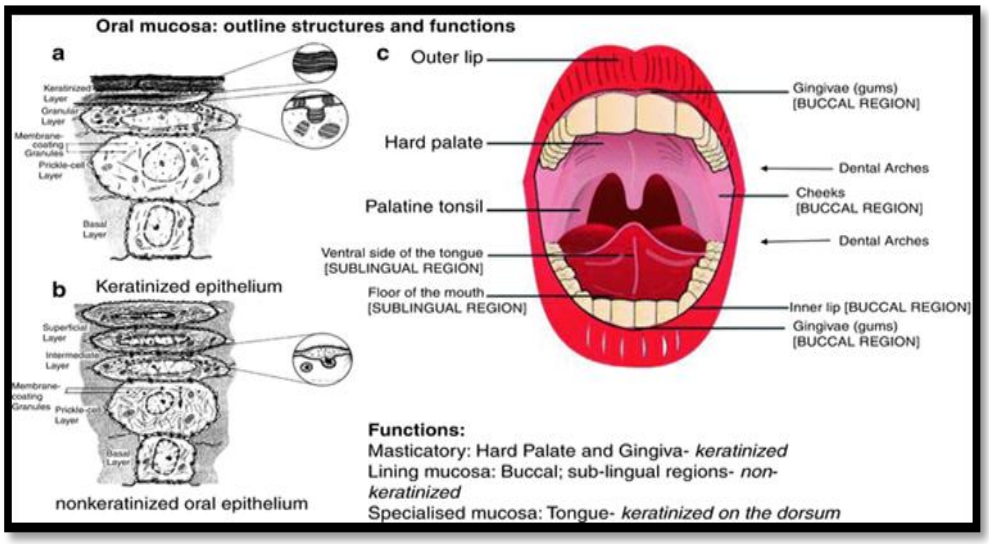

Fig. 1: Structure of oral mucosa.

Functions of oral mucosa

- Protection
- Sensation
- Secretion
- Thermal Regulation
- Permeability and absorption

Taste masking

In oral administration taste masking is the important parameter, the desirable taste is the better choice for pediatrics. It is one of the pharmaceutical parameter.

A. Types of taste

1. Sweet 2. Bitter 3. Umami
4. Salty 5. Sour

B. Approaches used to reduce bitter taste of drugs

1. Decreasing the drug solubility at the pH to 6.8 of saliva.
2. Drugs which involves with the taste receptor its nature and affinity can be changed.

C. Techniques of taste masking

1. Flavors and sweeteners
2. Prodrug
3. pH modifiers
4. Microencapsulation
5. Gelation technique

Ideal characteristics of oral medicated jellies

Important desirable characteristics of these dosage forms include no water requirement for swallowing purpose but it should dissolve or disintegrate in the mouth usually within fraction of seconds.

1. Compatible with taste masking.
2. Exhibit low sensitivity to altered environmental conditions such as humidity and temperature.
3. Allow high drug loading.
4. Be portable without fragility concern.
5. Leave negligible residue in the mouth after oral administration.
6. The drug and excipients property should not affect the orally disintegrating jelly.
7. Effective taste masking technologies should be adopted for bitter taste drugs.

Advantages

The performance of oral medicated jellies depends on the technology used during their manufacture. Various technologies have been developed that enable jellies to perform this unique function. Advantages of oral medicated jellies are as follows:

1. Oral medicated jelly is most convenient for disabled, bedridden patients, travelers and busy people, who do not always have access to water.
2. Rapid onset of action.
3. Cost effective.
4. Suitable during traveling where water may not be available.
5. Conventional manufacturing equipment.
6. Oral medicated jelly can be administer to the patients who cannot swallow tablets/cap., such as the elderly, stroke victims, patients with esophageal problems & patients who refuse to swallow such as pediatric, geriatric & psychiatric patients and thus improves patient compliance.
7. It can also be used for systemic delivery of drugs, which are prone to metabolism in the gut wall or liver.
8. Good chemical stability as conventional oral solid dosage form.
9. Good mouth feel property of jellies helps to change the perception of medication.

Disadvantages

1. As it is aqueous based preparation it needs appropriate packaging to maintain stability of drugs in various environment.
2. It may lead to unpleasant taste if not formulated appropriately.
3. It also shows the fragile, effervescence granules property.
4. Lack of physical resistance in standard blister packs.
5. Oral medicated jelly is hygroscopic in nature so must be keep in dry place.
6. It requires special packaging for properly stabilization & safety of stable product.

Need for development of jellies

The need for non-invasive delivery systems persists due to patient's poor acceptance and compliance with, existing delivery regimes, limited market size for drug companies and drug uses, coupled with high cost of disease management.

Patient factors

Orally disintegrating dosage forms are particularly suitable for patient for one reason find it inconvenient to swallow traditional tablets and capsules with an 8-oz of water. These include the following:

1. A patient with persistent nausea, who may be journey, or has little or no access to water.

2. Pediatric and geriatric patients who have difficulty in swallowing or chewing solid dosage forms.
3. Very elderly patients who may not be able to swallow a daily dose of antidepressant.
4. An eight-year old with allergies who desires a more convenient dosage form than antihistamine syrup.
5. Patients who are unwilling to take solid preparation due to fear of choking.

Challenges in formulating oral medicated jellies

I. **Hygroscopicity/Moisture sensitivity:** Several oral jelly dosage forms are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Hence they need protection from humidity and it requires specialized product packaging.

II. **Palatability:** It is a dreadful challenge for formulation scientist to mask the taste of bitter drug selected for oral medicated jelly. As most drugs are unpalatable, orally disintegrating drug delivery systems usually contain the medicament in a taste masked form. Hence, taste masking of the drugs becomes critical to patient compliance.

III. **Aqueous solubility:** Water soluble drugs possess various formulation challenges because they form eutectic mixtures, which result in freezing point depression and the formation of a glassy solid that may collapse upon drying because of loss of supporting structure during the sublimation process. Such collapsible structure can be prevented by jelly forming excipients such as almond gum that can induced crystallinity and impart rigidity to the formulation.

IV. **Dose/Amount of drug:** Molecules requiring high doses present mainly three challenges to the development of fast dissolve dosage forms; a) taste masking of the active ingredient, b) mouth feel or grittiness and c) Jelly size. The amount of drug in different dosage form will depend on the drugs degree of bitterness relative to its dose.

V. **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. the jelly size that is both easy to take and easy to handle is difficult to achieve.

VI. **Mouth feel:** The Oral medicated jellies should not disintegrate into larger particles in the oral cavity. The particles generated after disintegration of the Medicated Jellies should be as small as possible. They should leave minimal residue in mouth after oral

administration. Addition of flavors and cooling agents like menthol improve the mouth feel.

VII. **Sensitivity to environmental conditions:** Oral medicated jellies generally should exhibit low sensitivity to environment conditions such as humidity and temperature as most of the materials used in an oral medicated jellies are meant to dissolve with minimum quantity of water.

VIII. **Drug property:** some drug properties potentially affect the performance of jellies. For e.g. solubility, crystal morphology, particle size and bulk density of a drug can affect the final jelly characteristics, such as jelly strength and dissolution.

Molds for jelly formulation

There are different types of jelly molds available in market for preparation of jellies are as plastic molds, silicon molds, flower molds, copper molds, chocolate molds etc.

Fig. 2: Jelly molds.

Types of oral jelly

There are 3 types of jellies

1. Medicated jelly

These are used on mucus membrane and skin for their spermicidal, local anesthetics and antiseptic properties. These jellies contain sufficient amount of water. After evaporation of water, jellies provide a local cooling effect and residual film gives protection. These

medicinal film usually adheres well and gives protection but is easily removed by washing when the treatment is complete.

For e.g.: Ephedrine sulphate jelly is used as a vasoconstrictor to arrest the bleeding of nose. Phenyl mercuric nitrate – as a spermicidal contraceptive.

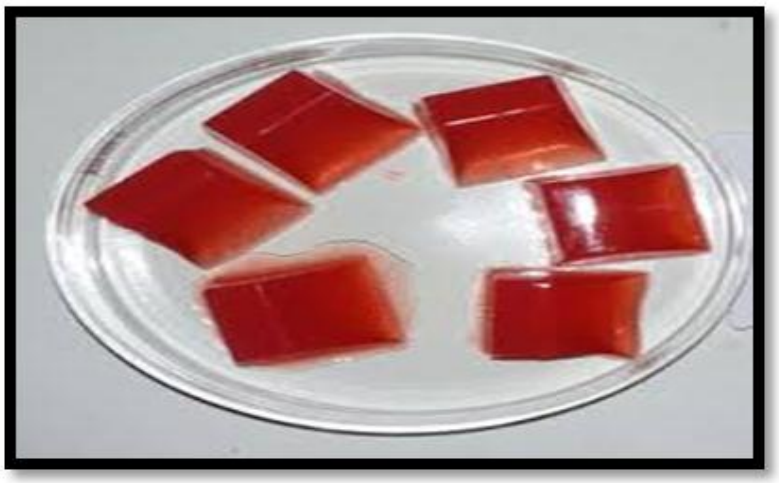

Fig. 3: Medicated jelly.

2. Lubricating jelly

Catheters, items of electro diagnostic equipment, such as cystoscopes and rubber gloves or finger stalls used for rectal and other examinations require lubrication before use. The lubricants must be sterile for articles inserted into sterile regions of the body, such as urinary bladder. For painful investigations a local anesthetic may be included as in Lignocaine Gel B.P.C.

Fig. 4: Lubricating jelly.

3. Miscellaneous jelly

These are meant for various applications like patch testing, electro cardiography.

a) Patch testing

Here jelly is the vehicle for allergens applied to the skin to detect sensitivity. Several allergens may be applied on one person. These testing helps to keep the particles separate.

b) Electro cardiography

It is used to reduce electrical resistance between the patient's skin and electrodes of the cardiograph, an electrode jelly may be applied. This contains Nacl to provide good conductivity and often pumice powder which when applied on to the skin removes part of the horny layer of the epidermis, the main layer of electrical resistance.

Fig. 5: Miscellaneous jelly.

Excipients used in oral jelly formulation

Fig. 6: Ingredients used in jelly formulation.

Drug selection criteria for formulation

1. Ability to permeate the oral mucosa.
2. Small to moderate molecular rate.
3. Partially non-ionized at the oral cavity's PH.
4. Low dose drug preferably less than 50mg are used.
5. Drug should have good stability in saliva and water.
6. Short half-life and frequent dosing drugs are unsuitable for medicated jellies.
7. Very bitter or unacceptable taste and odor drugs are unsuitable for these preparation.
8. Have the ability to diffuse and partition into the epithelium of the upper GIT.

A. Drug suitable for jelly examples

1) Anticoagulants: Dipyridamole, Dicoumarol.

2) Antifungal agents: Clotrimazole, Butaconazole nitrate.

3) **Antibacterial agents:** Cinoxacin, Ciprofloxacin hydrochloride, Clarithromycin

4) Anti thyroid agents: Carbimazole, Propylthiouracil

5) Local anesthetics: Lidocaine

6) Antimigraine agents: Dihydroergotamine mesylate, succinate

7) Analgesics & anti-inflammatory agents: Ibuprofen, Paracetamol

8) Anti-Diabetic agents: Metformin, Glibenclamide

9) Anthelmintic agents: Albendazole, Mebendazole

B. Gelling agents

These are usually hydrocolloids, which have been found appropriate for the formulation of gel like matrix. Some examples of them are as follows:

a. Tragacanth

The main hydrophilic component of tragacanth that gels in water has been named bassorin hence, tragacanth jellies are sometimes called bassorin paste. The amount of gum required for a preparation varies with its use:

I. For lubricating jelly 2 to 3%.

II. For dermatological vehicles about 5 %.

Tragacanth gum is used as an emulsifying and suspending agent in a variety of pharmaceutical formulations. It is used in creams, gels and emulsion formulations.

b) 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.

Advantage: Sodium alginate has an advantage over tragacanth that is available in several grade or standardized viscosity.

c) 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, gastro-retentive, colon-specific drug delivery systems. Also used as stabilizer in cosmetics.

Pectin is a very good gelling agent and is used in the preparation of many types of jellies including edible jellies.

d) 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. Gelatin is also widely used in food products.

e) Xanthan gum

It is widely used in oral and topical pharmaceutical formulations, cosmetics and food as suspending agent and stabilizing agent. It is also used as a thickening and emulsifying agent.

f) 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.

g) Agar

Agar-agar is vegetarian product & substitute to gelatin. It is obtained from algae & is White and semi-translucent. It has various applications such as thickener, gelling agent, texturizer, moisturizer, emulsifier, flavor enhancer, absorbent in pharmaceuticals & food products.

C. Sweeteners

1. 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.

2. Saccharin

It is an artificial sweetening agent. It is about 250-500 times sweet as sucrose. Particularly at higher concentrations it gives bitter or metallic aftertaste. It has excellent stability and water solubility.

3. Dextrose

They are anhydrous & monohydrate form of dextrose, among them anhydrous form is hygroscopic in nature. It is roughly used as 70 % sucrose.

Table 1: Various Sweeteners & Its sweetness in terms of sucrose.

Sweeteners	Sweetness corresponding to sucrose(X)
Sucralose	1000X
Saccharin	500X
Aspartame	250X
Xylitol	1X
Dextrose	0.75X
Sorbitol	0.5X

4. Sucralose

It is an artificial sweetener. Sucralose is obtained by replacing 3 hydroxyl groups with chlorine atoms in sucrose molecule. It is about 320 to 1,000 times as sweet as sucrose, twice as sweet as saccharin, and thrice as sweet as aspartame. Compared to sucrose onset of sweetness occurs slowly but sweetness remain for longer duration of time.

D. Coloring agents

Colorants are used for the following reasons:

1. Help in product recognition and differentiation.
2. Also used to match the flavor used in the formulation.
3. To provide aesthetic appearance to dosage forms & to increase patient acceptance.

According to the Food, drug and cosmetic Act of 1938 Colorants are classified as:

I. FD & C colors

II. D & C colors

III. External D & C

Table 2: Coloring agents.

Colors	Examples
Natural colors	Lycopene, beta carotene
Mineral colors	Mixture of red and yellow ferric oxides
Dyes	Crystal violet, safranin, methylene blue
Lakes	Aluminum lakes, calcium salts of FD & C dyes

E. Flavoring agents

Bitter taste of drugs can be prevented by the use of flavoring agents. Flavoring agents also enhances patient's compliance.

Table 3: Flavors used as per taste.

Taste	Flavors used
Acidic	Cherry, lemon, orange, grape fruit
Alkaline	Vanilla, mint, chocolate
Bitter	Orange, anise, lemon
Metallic	Grape , Berry
Sweet	Honey, raspberry, bubblegum, mint

F. Preservatives

Jellies are aqueous preparations which may allow the microbes to grow. Preservation must be selected to avoid any incompatibilities with the gelling agents, which may retard the shelf life of the product.

Some examples of them are as follows:

- Methyl paraben
- Propyl paraben
- Benzoic acid
- Benzalkonium chloride

G. Stabilizers

They are added in the formulations to prevent the drying of jellies. Some examples of them are as follows:

- Propylene glycol

- Sorbitol
- Chelating agent e.g. EDTA is added to prevent the sensitivity of bases and the medicaments towards heavy metals.

Preparation method of jellies

1. Jellies were prepared by heating and congealing method.
2. Jellies are prepared using freshly boiled and cooled distilled water as per composition listed.
3. Sucrose syrup prepared in water on heating and stirring at 80°C for about 90 minutes.
4. Weighed polymer powder was dispersed in 10 ml of water maintained at 90°C throughout the preparation.
5. The dispersion was stirred using a magnetic stirrer for 20 mins. to facilitate hydration of gelling agent.
6. Drug taken in to another beaker and solubilized using alcohol.
7. Simple syrup was added to it under continuous stirring.
8. The citric acid and preservatives were added under continuous stirring.
9. The final weight was adjusted with purified water, mixed, transfer to suitable molds, sealed and allow to cool that room temperature (25°±5°c) to form a jelly like texture.
10. Finally, when jelly set it is wrapped in gelatin paper and stored in dry place.

Fig. 7: Example of some formulated oral jellies.

Evalaution tests of jellies

1. Physical examination

The medicated jelly will be examined physically for appearance like texture, transparency and consistency, gumminess and grittiness. Grittiness is determined by rubbing the jelly between fingers. The oral jelly was also subjected for clarity, color, odor etc.

2. Viscosity

Viscosity had been measured using Brookfield Viscometer. As the system is non-Newtonian spindle no. 4 was used.

Formula for viscosity is given as:

$$\text{Viscosity in centipoise} = \text{Dial reading} \times \text{factor}$$

3. pH determination

The pH of all the jelly was determined using digital pH meter. 0.5 gm of the weighed formulation was dispersed in 50 ml of distilled water (50%) and the pH was noted.

4. Spreadability

For the determination of spreadability sample of jelly was applied between two glass slides and compressed to uniform thickness by placing 1000gm weight. The time required to separate the two slide moves over the lower slide was taken measure of spreadability.

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

Where m = weight tide to upper slide,

L = length moved on glass slide,

T = time taken.

5. Drug content

This evaluation is performed for every dosage form to assure the equality of content in drug substance. For drug content, ten jellies are selected & crushed in a mortar & then mixture equivalent to that of drug was taken & dissolved in 100 ml of volumetric flask containing 6.8 pH buffer & the final volume was made up to the mark. Then the solution was filtered & diluted appropriately, and analyzed spectrophotometrically using UV-visible double-beam spectrophotometer.

6. Stickiness and Grittiness

It is determined by rubbing the jelly between two fingers and then stickiness and grittiness is checked visually.

7. Weight variation

It is determined by the average weight of ten jellies as they are taken out of molds in a beaker and individually weighed and mixed.

8. Syneresis

Syneresis is defined as contraction & separation of water from the gel upon storage and the jelly preparation was evaluated after 24 hours at room temperature. One of the major cause for syneresis is using lesser concentration of gelling agent. Low acylated guar gum gels are mostly prone to syneresis.

9. Microbial studies

These studies are important parameter for determining the microbial profile of jellies. As jellies are more prone to microbial growth due to presence of water.

The jellies were tested for culturing pathogens on specific medium for E. coli, S. Aureus and P. Aeruginosa.

10. In-vitro taste analysis

5 ml simulated salivary pH was used to analyze the taste competency of prepared jelly. One jelly from each batch placed in 5 ml solution in a 50 ml beaker for 60 sec. to 120 sec, solution is the filtered respectively. By using UV, filtrates were examined for drug content.

11. In-vitro dissolution study

An in–vitro dissolution study will performed with USP basket apparatus using suitable dissolution medium. Dissolution medium was kept at 37°C ± 0.5°C and 50 rpm. The sample are withdrawn after 10, 20, 30, 40, 50, 60 minute and replaced with fresh media. The Sample ware determined for drug release using suitable analytical method.

12. Stability studies

Stability studies are determined according to ICH guidelines and can be evaluated by carrying out the prepared jelly. The jelly formulations are packed in aluminium foils & stored in polyethylene containers at 0°C, 25°C /60% RH for 90 days.

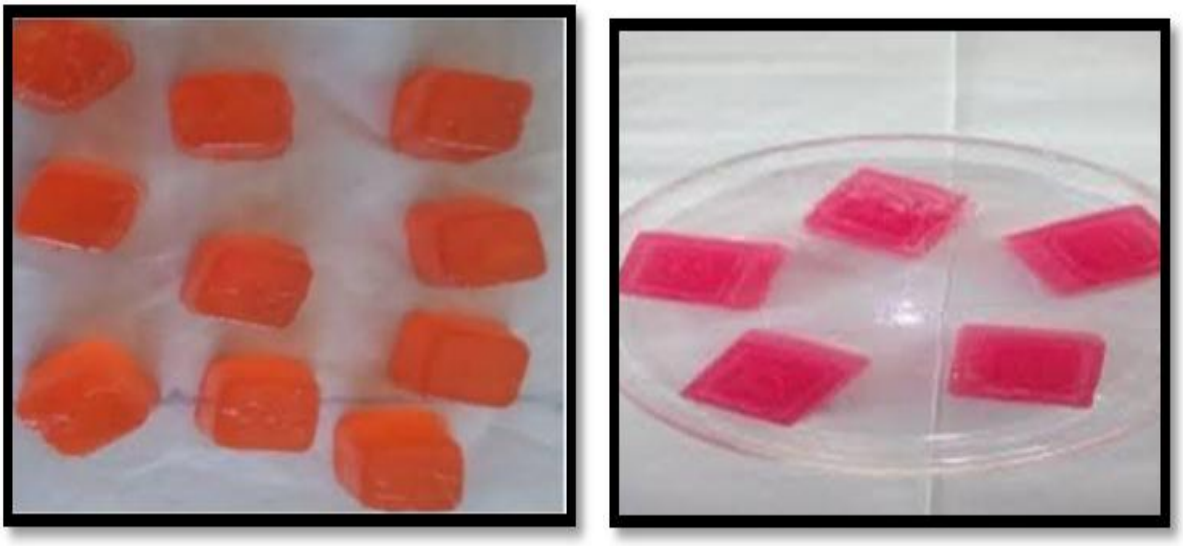

Fig. 8: Jelly formulations during stability studies.

Packaging of jellies

Jelly should be hermetically sealed in glass containers as well as plastic containers and pouches. A paraffin seal is not adequate to prevent spoilage of the product. Containers filled scalding hot (in excess of 83°C) need not be pasteurized as the hot jelly itself will sterilize the container.

Fig. 9: Glass containers for packaging of jellies.

Aspects for pediatric formulation

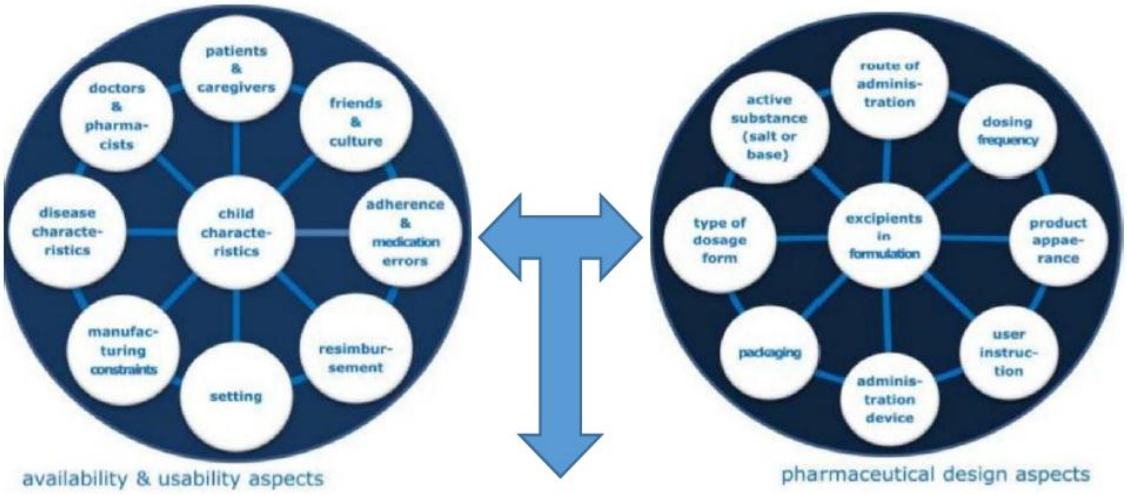

Fig. 10: Key aspects for pediatric formulation.

Key aspects involve the development of novel dosage forms such as jelly formulations, the safety of excipients, child acceptability and the importance of suitable dosing devices. The acquired knowledge is useful to formulation scientists as well as to doctors, pharmacists and caregivers when prescribing, compounding, dispensing or administering medicines to children.

Marketed formulations

Fig. 11: Kamagra oral jelly.

Fig. 12: Calorie mate apple jelly.

Table 4: Examples of marketed medicated oral jellies.

Sr. No.	Active ingredient	Application
1.	Isosorbide	Hydrocephalus
2.	Acyclovir	Viral infection
3.	Sildenafil	Erectile dysfunction
4.	Alendronate	Osteoporosis
5.	Amlodipine besilate	Hypertension
6.	Cilostazol	Chronic arterial obstruction
7.	Donepezil hydrochloride	Alzheimer's dementia
8.	Tadalafil	Erectile dysfunction
9.	Lactulose	Hyperammonemia

CONCLUSION

It may be concluded that the recent development of oral medicated jellies formulation can easily accepted by patients with dysphagia, pediatric and geriatric patients. Hence, patient compliant dosage form proves beneficial over conventional ones. It introduces the drug in a readily soluble form which might enhances the bioavailability of many poorly soluble drugs.

The present studies concludes that oral medicated jellies can be very promising drug delivery for effective doses to systemic circulation. These may also provide an advantage of preventing hepatic first pass metabolism. It is the novel approach which aims to improve safety and efficacy and also enhance patient compliance. Oral jellies are alternative to solid dosage form as they possess both solid and liquid properties and having easy administration without ingestion of water.

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