

Review on Formulation and Development of Oral Medicated Jellies

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ABSTRACT: Oral medicated jellies developed dated back to 20th century remain popular among the consumer and hence it has Continued commercial production Oral medicated jellies are the palatable solid dosage form administered in the oral cavity meant to be dissolved in mouth or pharynx for its local or systemic effect. Oral medicated jellies provide several advantages as a pharmaceutical formulation however with some disadvantages. Oral medicated jellies as a dosage form can be adopted for drug delivery across buccal route labial route gingival route and sublingual route. Oral medicated jellies are available as over the counter medications in flavor based of mango pineapple strawberry and chocolate etc containing drug for antistatic erectile dysfunction Arteritis antihypertensive sore throat. Ones weekly oral medicated jellies are approved in 2012 by ministry of health labour and welfare of japan as the world first drug for osteoporosis in a jelly formulation. The y are formulated using heating and congealed technique. It serve as a novel dosage form with wide applications in pharmaceuticals nutraceuticals and over the counter medicines. The review focuses various aspects of oral medicated jellies formulation providing an insight to the formulation scientists on novel applications of this drug delivery system.

KEYWORDS: Oral medicated jellies chronic illness, anaesthetic, hypertension, nutraceuticals.

I. INTRODUCTION:

Oral medicated jellies are the palatable Solid dosage form administered in the oral cavity, meant to dissolve in mouth or pharynx for its local or systemic effect. Patients are usually comfortable with oral drug delivery system since it is non-invasive and usually offers low cost of treatment. Also the safety, efficacy and cost effectiveness of

oral drug delivery system enhance its patient compliance. Current paediatric formulation has so many drawbacks. Most of the paediatric formulation available in the market are tablet, capsule, syrup, solution and drops. For liquid formulation dose volume is a major consideration. Only dose volume less than 5ml is recommended for children under five year and less than 10ml is recommended for children of five year and older.

Japanese pharmacopeia define Jellies meant for oral administration as non flow able glutinous preparation of definite size and shape, meant for oral administration. Jellies can be define as semisolid preparation that are transparent, translucent or no greasy, intended for internal or external applications. The sources from which jellies can be prepared are natural gum like tragacanth, pectin, sodium alginate or form synthetic derivatives like methyl cellulose and sodium carboxyl methyl cellulose. As these jellies have eye catching appearance, pleasant taste and easy to handle, everyone prefers jelly over oral liquid or tablet.

Over a decade, the demand for development of oral medicated jellies (OMJs) has enormously increased as it has significant impact on the patient compliance. Oral medicated jellies are appreciated by a significant segment of population particularly who have difficulty in swallowing. It has been reported that Dysphasia (difficulty in swallowing) is common among all age and group and more specific with pediatric, geriatric population along with institutionalized patients and patients with nausea, vomiting and motion sickness complications. Common among all age group, 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. OMJs with good taste and flavor increase the acceptability of bitter drug by various group of population.

“Jelly can be define as transparent or translucent non-greasy, semisolid preparation meant for external as well as internal applications” the medicated jelly has through years gained increasing acceptance as a drug delivery system. Several ingredient are now incorporated in medicated jelly. i.e.drug which required fast onset of action, drug which have major absorption site is stomach and small intestine. they may be prepared from natural gums such as tragacanth, pectin, sodium alginate or from synthetic derivatives of natural substance such as methyl cellulose and sodium carboxyl methyl cellulose. Children may consider jelly as more preferred method of drug administration compared with oral liquid or tablet. The use if medicated jelly is feasible as local treatment of disease of the oral cavity as well as treatment of systemic condition.



Figure 1. Jellies

II. TYPES OF JELLIES:

a)Medicated jelly

These are mainly used over mucous membrane and skin and they posses spermicidal local anaesthetic, and antiseptic properties. These jellies hold adequate amount of water which after evaporation gives a local cooling effect and residual film provide protection

Example: Ephedrine sulphate jelly is used to seize the bleeding of nose since it is vasoconstrictor.

b)Lubricating jelly:

These jellies are intended for lubrication of equipment used in diagnosis like surgical glove, catheters, cytosopes.

c)Miscellaneous jelly:

These are meant for various applications like patch testing, eletrocardiography.

Jellies contain sufficient water. After evaporation of water jellies provide a local cooling effect and residual film gives protection. For example, ephedrine sulphate jelly is used as a vasoconstrictor to arrest the bleeding of nose. Oral medicated jellies should depict some ideal characteristics to distinguish them from traditional conventional dosage form. Important desirable characteristics of these dosage form include no water requirement for swallowing purposed but it should dissolve or disintegrate in the mouth usually within fraction of second

Gelling agent should leave minimal or no residue in mouth after oral administration, compatible with pleasing mouth feel.

- Be compatible with taste masking .
- Effective taste masking technologies should be adopted for bitter taste drug.
- Be portable without fragility concern.
- Leave negligible or no residue in the mouth after oral administration.
- Allow high drug loading
- The drug and excipients property should not affect the orally disintegrating tablet.

Challenges in formulating oral medicated jelly

- **Palatability:** Masking taste of bitter drug and enhancing taste directly related to patient compliance.
- **Hygroscopicity:** some oral jelly dosage form are hygroscopic and they need protection from humidity so need specialized product packaging.
- **The drug property:** solubility, crystal morphology, particle size and bulk density of affected the final jelly characteristics.
- **Mouth feel:** medicated jellies leave minimal or no residue in mouth after oral administration.

OBJECTIVES OF ORAL MEDICATED JELLIES :

To developed a formulation which is dissolved in mouth of pharynx which is local or systemic effect

- 1.To increase patient compliances
2. To used poorly soluble drug in medicated jelly
- 3.Formulation of chipper dosage form then conventional formulation.

Advantages of medicated jellies:

- 1.it can be administered easily i.e. anytime,anywhere as it is easy to handle & doesn't required water.
- 2.Therapeutic action of drug can be terminated by spitting it before complete ingestion of medicated jelly.

3. It serves as an ideal method of drug delivery for dysphasia patients as it reduces the risk of aspiration.
4. Good mouth feel property of jellies helps to change the perception of medication.
5. Rapid onset of action.
6. The treatment can, if required, be terminated at any time.

Disadvantages of medicated jelly:

- As it is an aqueous based preparation it needs appropriate packaging to maintain stability in various environments.
- It may lead to an unpleasant taste if not formulated appropriately.

III. EXPERIMENTAL WORK:

Formulation of Oral Medicated Jelly

Oral medicated jelly can be prepared by using gelling agents like sodium alginate, gelatin, guar gum, xanthan gum, citric acid was used as pH modifier simple syrup (0.02%) can be used as a preservative. Purified water up to 100% as a vehicle can be used accurately weight polymer powder were dispersed in 10ml of purified water maintained at 90°C. The dispersion was stirred using a magnetic stirrer for 20 min. To facilitate the 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.

Formula of medicated jellies

Sr. No.	Ingredients	F1	F2	F3	F4	F5	F6
1	Drug	40 mg	40 mg	40 mg	40 mg	40 mg	40 mg
2	Gelatin	3.5 gm	4 gm	4.5 gm	---	---	---
3	Dextrose	1 gm	---	1 gm	1 gm	1 gm	1 gm
4	Citric acid	0.5 gm	0.4 gm	0.5 gm	0.5 gm	0.5 gm	0.5 gm
5	Methyl parab	0.1 gm	0.1 gm	0.1 gm	0.1 gm	0.1 gm	0.1 gm

	en						0 gm
6	Sucrose	33.4 gm	33.4 gm	33.4 gm	34.4 gm	34.4 gm	34.4 gm

Preparation method

- All ingredients will be weighed accurately.
- In one beaker sugar syrup will be prepared by adding 33.4 gm sugar in beaker and make up the volume to 50 ml.
- To that solution gelling agent will be added with constant stirring and heated to dissolve to achieve desired stiffness.
- After boiling the boiling above solution preservatives will be added to that solution mix through and uniformly.
- Now, drug is weighed accurately dissolved in a suitable vehicle and added before jelly is allowed to set mix thoroughly.
- The whole solution was transferred in moulds and then allowed it for cooling and settling undisturbed by proper covering the moulds to avoid exposure environments.

Evaluation Of Medicated Jelly

Physical appearance:

The medicated jelly was examined for physical appearance in terms of clarity, texture and consistency.

Stickiness and grittiness: Texture of the medicated jelly in terms of stickiness and grittiness had been evaluated by visual inspection of the product after mildly rubbing the jelly sample between two fingers.

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

$$S = m * L / T$$

Where m = weight tide to slide

L = length moved on glass slide

T = time taken

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

▪ □ **pH:** The pH of all the jelly was determined using digital pH meter. 0.5gm of the weight formulation was dispersed in 50ml of distilled water and pH was noted.

▪ □ **Drug content:** the jellies are selected and crushed in a mortar and then mixture equivalent to that of drug was and dissolved in 100ml of volumetric flask containing 6.8pH buffer and final volume was made up to the mark. Then the solution was filtered and diluted appropriately, and analysed spectro photometrically using uv spectrophotometer.

▪ □ **Stability studies:** The jellies formulation were packed in aluminium foil and stored in polyethylene containers at 0°C, 25°C/60%RH for 90



Figure 2: jellies made using gelatine

IV. RESULT AND DISCUSSION
In vitro evaluation of prepared medicated jellies
Physical observation

The medicated jellies were evaluated visually for the clarity, colour, odour, presence of any type of type particles and texture. The texture was evaluation in term by mild rubbing the gel between two fingers. Appearance must be appealing for the patient compliance and acceptance

Ingredients used in Medicated Jellies

1st Portion

Ingredients	Quantity
Water	9gm
Liquid	103gm
Sugar	67gm

2nd Portion

Ingredients	Quantity
Gelatine	10gm

Sorbitol	6.56gm
Water	64gm

Taste and palatability

It was carried out on a trained panel of six healthy volunteers of age group 20-32years and body weight 56-70kg. The study protocol followed the ethical principles forensically research involving human subjects. The bitterness was recorded immediately and at interval of 1 min up to 10 min.

Weight variation

Ten jellies were taken and weight of individual jellies was determined by using weighting balance of analytical grade.

Stability studies

For the stability jelly, formulation were packed in aluminum foil, transfer to high-density polyethylene container, tightly closed, and stored at room temperature for 60 days.

The sample were characterized for change in various parameters such as appearance, sugar crystallization, stiffness, and synthesis at the end of 60 days. Reading of freshly made jellies were used as a reference standard for subjective evaluation.

Taste and palatability of jellies

Time	Medicated jelly
After 1 min.	Sweet & palatable
After 2 min.	Sweet & palatable
After 3 min.	Sweet & slightly, sour palatable
After 4 min.	Sweet, acceptable sour & palatable
After 5 min.	Sweet, acceptable sour & palatable
After 6 min.	Sweet, slight tarturate & palatable

V. SUMMARY AND CONCLUSION

▪ □ Aim of the present study was to develop and evaluation of oral medicated jellies using various gelling agent with higher, medium and lower concentrations.

- Jellies are prepared by using four different polymers with different concentrations.
- Preformulation studies were conducted on drug such as melting point determination, spectroscopic analysis, FTIR studies.
- Batches (F1-F6) of prepared jelly were subjected
- Appearance, pH, viscosity, Spreadability, contact, uniformity, synereses, stickiness, etc
- Prepared by heating and congealing method using sucrose syrup and syrup polymer
- All formulation shows better spreadability.
- The viscosity of all formulation were determined by brookfield viscometer.
- All formulation have uniformity of content.
- The formulation of jelly is an easy and timesaving process
- It is a formulation which is more organoleptically accepted by the paediatric geriatric.

CONCLUSION

From all evaluation to be concluded that prepared medicated jelly is more organoleptically accepted particularly by patient with disability in ingestion of food and drink, in other word, those having difficulty in mastication and swallowing. Prepared medicated jellies is cost wise cheap, acceptable and more stable over other palonosetron hydrochloride formulations available market.



Figure no 3. Medicated jelly

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