



Formulation and Evaluation of Medicated Oral Jelly of Vitamin B-Complex Capsule.

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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.

The main purpose of medicated jelly is made because in some regions for example Jain cast people don't use any non vegetarian food for their consumption on daily routine , vitamin B-Complex Capsule which contains a capsule which is made of bone of animals then it is a type of non vegetarian food.

So the main purpose of these medicated jelly is pureed vegetarian food also easy to eat anywhere, mostly children and adults also used .

In medicated jelly also used Becosule capsule which is completely vegetarian food and easy to use to cure disease and used as food .

KEYWORDS:-

- Medicated oral jelly, pharmaceutical jelly, Vitamin B-Complex Capsule, bioavailability

INTRODUCTION:

- Definition: "Jelly can be defined as transparent or translucent non-greasy, semisolid preparations meant for external as well as the internal application". Or jellies are water-soluble bases prepared from natural substances
- The medicated jelly is mainly used for oral diseases as well as systemic diseases. It is useful for paediatric and psychotic patients because it's like candy, and they can easily take this medication as having attractive colour and sweet taste, and they love chewing the jelly having different shapes and sizes
- . Jellies are traditionally prepared using gelatin. The material is dissolved in hot water, and gelation occurs on cooling in the refrigerator.
- Many psychotic patients are medicinal phobic who are afraid of taking medicine, so this preparation is most beneficial over that type of fear, and moreover, it is attractive in appearance for those patients as well as paediatrics and geriatric patients. Trazodone HCl antidepressant drugs are incorporated in jelly and given to that patient; in this way, we could administer medicine to them without bringing this to their attention; this is how we can treat psychotic patients.
- Children may consider jelly as a more preferred method of drug administration compared with oral liquid or tablets. The use of medicated jelly is feasible as local treatment of disease of the oral cavity as well as treatment of systemic condition.



II. TYPES OF JELLIES:

- a)Medicated jelly

These are mainly used over mucous membrane and skin and they possess 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 the nose since it is vasoconstrictor.

- b)Lubricating jelly:

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

- c)Miscellaneous jelly:

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

- 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 the nose. Oral medicated jellies should depict some ideal characteristics to distinguish them from traditional conventional dosage form.

Oral Medicated Jellies :-

- Oral Medicated Jellies have been found to be the choice for Psychiatric and patients suffering from stroke, thyroid disorder, Parkinson's diseases and multiple sclerosis, nausea, vomiting and motion sickness.
- At present, OMJs are the only quick-dissolving dosage form recognized by FDA and listed in Approved Drug Products with Therapeutic Equivalence Evaluations (also called the Orange Book). Although chewable tablets have been on the market for some time, they are not the same as the new OMJs.
- Patients for whom chewing is difficult or painful can use these new tablets easily. OMJs can be used easily in children who have lost their primary teeth but do not have full use of their permanent teeth.
- OMJs release drug in the mouth and for absorption passed through local oromucosal tissues and through pregastric (e.g., oral cavity, pharynx, and oesophagus), gastric (i.e., stomach) and postgastric e.g., small and large intestines) segments of the gastrointestinal tract (GIT

VARIOUS COMPONENTS OF MEDICATED JELLY FORMULATION:-

I. Gelling Agent

- These are hydrocolloids, which form gel-like matrices. It dissolves in liquid phase and forms a weak cohesive internal structure. Examples of gelling agents:

a) 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.

b) 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 stabilisers in cosmetics.

c) Tragacanth

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

d) Gelatin

- Gelatin is generally used as a gelling agent in pharmaceutical preparation, vitamin capsules, cosmetic technology, & photographic emulsions. Also used in implantable delivery systems to deliver drugs suspended in biodegradable matrices.

e) Xanthan Gum

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

II. Sweeteners

a) Sucrose

- Sucrose was the 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 crystallisation of sucrose.

Table 1: 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

b) Dextrose

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

c) 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

d) 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.

e) Sucralose:

- It is an artificial sweetener. It is thermostable and also remains stable in a 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 remains for a longer duration of time.

III. Colouring agents:

Colourants are used for the following reasons:

- a) To provide aesthetic appearance to dosage forms
- b) To increase patient acceptance
- c) To maintain colour uniformity of the dosage form.

Types of Colouring agents

a) Natural Colours

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

b) Mineral Colours

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

c) Dyes

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

d) 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.

IV. Flavouring Agents

- Table 2: Flavours used as per taste taste:

Taste Flavours used

- Acidic Orange, lemon, cherry,
- Alkaline Vanilla, chocolate, mint
- Bitter Orange, anise, lemon
- Metallic Grape, berry
- Sweet Honey, chocolate, raspberry,

V. Preservatives:

- Jellies are prone to microbial attack. Preservation is must in order to avoid at all any incompatibilities between gelling agents & to retain the shelf life of product.
- Eg: Methyl Paraben, PropylParaben, Benzoic Acid,
- Benzalkonium Chloride, Chlorhexidine acetate.

VI. Stabilisers

- Stabilisers are used to maintain desirable properties of
- product .It is used to prevent the drying of jellies.
- Examples: Propylene glycol and Sorbitol. Chelating
- Agents are used to avoid any reactivity between base or medicament with heavy metals e.g. EDTA.

Table 3: Various components of oral medicated jellies

- Gelling agent Sodium alginate, pectin,
- Sweeteners Sucrose, dextrose, sucralose, Colouring agents Natural colours, mineral
- **Flavouring agents** :- Orange, lemon, vanilla, mint
- Preservatives Methylparaben, Propyl
- Stabilizers Propylene glycol, Sorbitol

Ideal Characteristics of Omjs:-

- Be compatible with taste masking.
- Effective taste masking technologies should be adopted for bitter taste drugs.
- Be portable without fragility concern
- Leave negligible or no residue in the mouth after oral administration.
- Exhibit low sensitivity to altered environmental conditions such as humidity and temperature.
- Allow high drug loading.
- Adaptable and amenable to conventional processing and packaging equipment at nominal expense.
- The drug and excipients property should not affect the orally disintegrating

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 forms are hygroscopic and they need protection from humidity so need specialised product packaging.
- The drug property: solubility, crystal morphology, particle size and bulk density affected the final jelly characteristics.
- Mouth feel: medicated jellies leave minimal or no residue in mouth after oral administration.
- Aqueous solubility:-] Water soluble drugs pose 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 collapse sometimes can be prevented by using various jelly forming excipients such as almond gum that can induce crystallinity and hence, impart rigidity to the amorphous composite.
- 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 :-Many drug properties could potentially affect the performance of jellies For example, the solubility, crystal morphology, particle size and bulk density of a drug can affect the final jelly characteristics, such as jelly strength and dissolve

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:

- It can be administered easily i.e. anytime,anywhere as it is easy to handle & doesn't require water.
- Therapeutic action of drug can be terminated by spitting it before complete injection of medicated jelly
- It serves as an ideal method of drug delivery for dysphagia patients as it reduces the risk of aspiration.
- Good mouth feel properties of jellies help to change the perception of medication.
- Rapid onset of action.
- The treatment can, if required,be terminated at any time.
- Conventional manufacturing equipment.
- Cost effective.
- Good chemical stability as conventional oral solid dosage form
- Allow high drug loading.
- Provides rapid drug delivery from dosage forms.
- Adaptable and amenable to existing processing and packaging Machinery.

- Rapid onset of action

Disadvantages of medicated jelly:

- As it is aqueous based preparation it need to appropriate packaging to maintain stability of drug in various environment.
- It may lead to unpleasant taste if not formulated appropriately.

Limitations of Omjs :-

1. Cost-intensive production process;
2. Lack of physical resistance in standard blister packs;
3. OMJ requires special packaging for proper stabilisation & safety of stable products.
4. It is also shows the fragile, effervescent granules

What is vitamin B-Complex:-

E.g:- BECOSULE CAPSULE:-



What is the use of BECOSULES CAPSULES?

- Becosules capsule is a multivitamin that promotes overall health and wellness by improving metabolism and tissue repair. It aids in the fight against infections by improving immune function.
- It is also used to treat sore tongues, mouth ulcers, and to keep hair, skin, and nails healthy.

Medical Advantages are:-

- It boosts collagen production, a protein required for the growth and development of hair, skin, and nails.
- It increases energy levels.
- Thiamine (vitamin B1) aids in the production of certain neurotransmitters as well as the execution of several enzyme processes.
- Riboflavin (vitamin B2) is required for the breakdown of fats, proteins, and carbohydrates into energy.
- Niacinamide (vitamin B3) is required for tissue respiration, macromolecule synthesis, and coenzyme activation.
- Calcium pantothenate aids in the utilisation of stored carbohydrates for energy production as well as the preservation of blood vessel integrity.
- Folic acid (vitamin B9) functions as a coenzyme in the formation of red blood cells and nucleic acid (DNA).
- Vitamin B12 helps to strengthen the nervous system.

Medicinal Benefits:+

- It increases the production of collagen, a protein needed for growth and development of hair, skin and nails.
- It boosts energy levels.
- Thiamine (vitamin B1) helps to produce certain neurotransmitters and carry out several enzyme processes.
- Riboflavin (vitamin B2) is essential for breakdown of fats, proteins and carbohydrates to produce energy.

- Niacinamide (a form of vitamin B3) is necessary for tissue respiration, macromolecules synthesis and activation of coenzymes.
- Calcium pantothenate helps to use stored carbohydrates for producing energy and also for preserving blood vessel integrity.
- Folic acid (vitamin B9) acts as a coenzyme in the synthesis of red blood cells and nucleic acid (DNA).
- Vitamin B12 strengthens the nervous system.

Directions for Use:-

- Take the dosage as prescribed by a doctor. Swallow the capsule with a glass of water.

Side effects:-

- It is generally safe and doesn't cause any side effects if used as prescribed. However, if you experience any side effects, please consult a doctor.

AIM:- FORMULATION AND EVALUATION OF MEDICATED ORAL JELLY OF VITAMIN B-COMPLEX CAPSULE .

OBJECTIVE:-

1.To increase patient compliances

2. To used poorly soluble drug in medicated jelly

EXPERIMENTAL WORK:-

Material And Methods for jelly preparation:-

Material used in jelly formulation

Table:-

SR No	Name of Ingredients	Quantity
1	Diabetic sugar (Saccharin)	0.6 gm
2	Lemon juice	5 ml
3	Custard powder	7gm
4	Vitamin B-Complex Capsule	1.9 gm
5	Water	QS

VARIOUS COMPONENTS OF MEDICATED JELLY FORMULATION:-

Diabetic sugar (Saccharin):-



- Saccharin is an artificial, or nonnutritive, sweetener that is used in the production of various foods and pharmaceutical products including:
 - Baked goods

- Jams
 - Chewing gum
 - Drinks
 - Tinned fruit
 - Medicines and
 - Toothpaste
- It is 200 to 700 times sweeter than sucrose (table sugar), does not raise blood sugar levels and like all nonnutritive sweeteners has no calories.
 -
 - Saccharin is unstable when heated but does not react chemically with other food ingredients, which makes it good for storage.

Lemon juice:-

- Benefits of Lemon Juice for Your Body
- Relieves a sore throat. ...
- May prevent and help fight cancer. ...
- Prevents kidney stones. ...
- Aids in digestion. ...
- Helps regulate blood sugar. ...
- Promotes weight loss. ...
- Helps clear skin. ..

Custard powder:-

- Custard powder originated as a boon for people who wanted an alternative to eggs. It looks a lot like cornflour and the reason being that the base used is cornstarch along with salt and flavourings. It is an ingredient which has aided everyone to make custard in a jiffy.

- It is a good alternative for people who want to avoid eggs. It thus aids in minimising the cholesterol levels in a custard.

Vit B-Complex Capsule (e.g- Becosule capsule):-



- Becosules capsule is a multivitamin that promotes overall health and wellness by improving metabolism and tissue repair. It aids in the fight against infections by improving immune function. It is also used to treat sore tongues, mouth ulcers, and to keep hair, skin, and nails healthy

PREPARATION OF ORAL MEDICATED JELLIES:-

- 1) Take all required ingredients which is used in formulation of medicated jelly
- 2) Take normal range of water and then add custard powder in required quantity
- 3) Then mix and proper dissolve powder into water as like a slurry or paste
- 4) After that in another beaker take a given quantity of Saccharin or sugar and mix into normal water, then properly dissolve and provide a heat using a burner.
- 5) Then add lemon juice in continuous stirring
- 6) Then add custard powder solution into sugar solution beaker and stir it continues
- 7) It produces thick paste of jelly after normal cooling solution add Capsule drug into this mixture with continue stirring
- 8) The paste is transferred into container which is provided proper jelly shape
- 9) It store into refrigerator for 2_3 hrs
- 10) After that medicated jelly is produced, it is easy to eat

EVALUATION TEST OF ORAL MEDICATED JELLIES:-

a) Physical evaluation

- The medicated jelly can be examined physically for appearance like clarity, texture, transparency, consistency.

b) Stickiness and grittiness

- Texture of the medicated jelly in terms of stickiness and grittiness can be determined by mildly rubbing the jelly between fingers

c) PH

- PH of jelly can be measured using a digital PH meter. 0.5 of the weighted formulation was dispersed in 50 ml of water and the PH should be noted.

d) Viscosity

- Viscosity was determined using Brookefield viscometer. As the system is non-Newtonian spindle no: 4 can be used.

e) Spreadability

- 2.5g jelly should be placed in between 2 glass slides and compressed to proper thickness by keeping 1000g weight for 5 min.
- The time in seconds needed to separate 2 slides were taken. Less Time interval to cover the distance of 7.5 cm showed better spreadability.
- $S = W * L / T$ Where IS = spreadability W = weight tied to upper slide L = length of glass slide T = time required to separate 2 slides.

f) Syneresis

- Syneresis is defined as contraction and separation of water from gel upon storage. One of the major causes for it is using a lesser concentration of gelling agents. Low acylated guar gum gels are mostly prone to syneresis.

g) 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 tarturated & palatable

h) Stability studies

- For the stability jelly, formulations were packed in aluminium foil, transferred to high-density polyethylene containers, tightly closed, and stored at room temperature for 60 days.
- The samples were characterised for change in various parameters such as appearance, sugar crystallisation, stiffness, and synthesis at the end of 60 days. Reading of freshly made jellies were used as a reference standard for subjective evaluation.

OBSERVATION TABLE:-

SR.NO	PHYSICAL EVALUATION TEST	OBSERVATION
1	Colour	Yellow colour (vanilla flavour)
2	Odour	Sweet taste
3	Solubility	Soluble
4	Feel on application	Smooth, smoothly texture
5	Appearance	Clear appearance
6	PH	8.1

APPLICATIONS

- 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 more convenient dosage form than antihistamine syrup.
- A patient who has no access to water for consuming dosage form.

CONCLUSION:-

- From all evaluation to be concluded that prepared medicated jelly is more organoleptically accepted particularly by patients with disability in ingestion of food and drink, in other word, those having difficulty in mastication and swallowing. Prepared medicated jellies are cost wise, cheap, and acceptable.

- physicochemical parameters like appearance, stickiness, pH, viscosity, spreadability, stability studies, drug release, and content uniformity.
- medicated jelly showed acceptable and comparable appearance, pH, viscosity, Spreadability, stability studies, drug release, and content uniformity



- The main purpose of medicated jelly is to it is pure vegetarian jelly which is the easy to administer, the drug is easy to swallow.
- Because the capsule is made up of bone extraction process,so it is non vegetarian part as compared to jelly it is pure vegetarian food so it is easy to administer.
- So that is the only one reason of preparing Medicated jelly.

REFERENCE:-

- FORMULATION AND EVALUATION OF MEDICATED ORAL JELLY :- Vaishali S. Kadam * 1 Jayshri Kendre 1, G. R. Shendarkar 2and S. Sangita Kadam 3Department of Pharmaceutics 1, Kandhar College of Pharmacy, Kandhar, Nanded - 431714, Maharashtra, India. *International journal of pharmaceutical sciences and research
- Pharmaceutical Jellies: A novel way of drug delivery:- Sruthi Sunil*, Dr. Umesh Kumar Sharma, S.A Arati Department of Pharmaceutics, Mar Dioscorus College of Pharmacy, Hermongiri Vidyapeetam, Alathara, Sreekariyam - 695017, Kerala, Thiruvananthapuram, India. *Sruthi Sunil et al /J. Pharm. Sci. & Res. Vol. 12(7), 2020, 904-909
- Review on Formulation and Development of Oral Medicated Jellies :- Ms. Pranita I. Rathod, Prof. V. V. Deshpande, Mr. Shadab ShaikhMs. Shreya B. Pathare, Ms. Shweta M. Nawghare, And Ms. Shweta S. Dhamankar. ¹B-Pharma student Ishwar Deshmukh Institute of pharmacy, Digras, Maharashtra, India²professor, Department of Pharmaceutics, Ishwar Deshmukh Institute of pharmacy, Digras, Maharashtra, India. *International Journal of Pharmaceutical Research an Applications Volume 7, Issue 4 July-Aug 2022, pp: 174-179
- ORAL MEDICATED JELLIES – A REVIEW :- S. Sarojini*¹, K. Anusha¹, Ch. Maneesha¹, M. A. Mufaquam¹, B. Deepika², Y. Krishna Reddy ²Nagaraju Kandukuri ²1 Department of Industrial Pharmacy, Nalanda College of Pharmacy, Nalgonda, Telangana. ²Department of Pharmaceutics, Nalanda College of Pharmacy, Cherlapally, Nalgonda, Telangana. *World Journal of Pharmaceutical Research SJIF Impact Fact8.074 Volume 7, Issue 6, 352-365. https://www.researchgate.net/publication/337394779_ORAL_MEDICATED_JELLIES_-_A_REVIEW_Corresponding_Author
- For basic information we used:-<https://share.upmc.com/2014/08/7-health-benefits-lemon-juice/>
- Custard powder general information:-https://www.google.com/url?sa=t&source=web&rct=j&url=https://m.tarladalal.com/glossary-custard-powder-512i&ved=2ahUK Ewi7v_G_gcP-AhV5SSWwGHYwIAN0QFnoECFMQAQ&usg=AOvVaw3D7Ze1DxeAo_VA7z4x2jPxE
- https://www.google.com/url?sa=t&source=web&rct=j&url=https://www.sciencedirect.com/science/article/pii/S1319016422001967&ved=2ahUKEwjJlt_ggcP-AhUrTWwGHYtQDWgQFnoECBAQAQ&usg=AOvVaw2_a2nq0z-xqWE8DaygDOVo
- https://www.google.com/url?sa=t&source=web&rct=j&url=https://www.diabetes.co.uk/sweeteners/saccharin.html&ved=2ahUKEwjYscqD_gsP-AhX-T2wGHcIPDn0QFnoECAAsQAQ&usg=AOvVaw0FfeSXkiln6hvw-3d9ae9A
- For Drug Related information:-<https://cashkaro.com/blog/becosule-capsule-uses-dosage-side-effects-precautions-more/27939>