FORMULATION AND EVALUATION OF HERBAL ORAL MEDICATED JELLIES OF GLYCICRRHIZA AND SPEARMINT

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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 chocked by water during administration liquid formulation with high viscosity which should be eliminated, thus it has been develop 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 accepted by patient with dysphagia, paediatric and geriatric patients, hence patient compliant dosage form proves beneficial over conventional ones. The aim of this review is to addresses briefly about its advantages, disadvantages, gelling agents, excipients, method for preparation, evaluation parameters and its significance over conventional form of drugs. Oral medicated jelly composed of Glycicrrhiza and Spearmint for the most part has a mouth refreshing properties as nicely as its kind of is antitussive, cough suppressant and also kind of treats essentially GIT upset, which is quite significant.

KEYWORDS: Oral medicated jelly, oral route, patient compliance, gelling agent, dysphagia, antitussive, GIT upset, mouth freshener, cough suppressant, glycicrrhiza, spearmint.

INTRODUCTION
“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 such as tragacanth, pectin, alginates, and boro glycerine or from synthetic derivatives of natural substances such as cellulose and sodium carboxy methyl cellulose or from synthetic derivatives of natural substances such as methylcellulose and sodium carboxymethylcellulose. [1]

A sort of generally ideal dosage regimen in the drug therapy of any disease mostly is the one, which immediately attains the desired definitely therapeutic concentration of drug in plasma (or at the site of action) and maintains it generally constant for the fairly kind of entire duration of treatment in a really particularly major way. Drugs for all intents and purposes are definitely sort of more frequently taken by generally very oral administration in a definitely major way, contrary to popular belief. It generally really is considered most natural, uncomplicated, convenient, for all intents and purposes safe for the most part basically means of administering drugs, generally greater flexibility in dosage form design, basically really ease of production and basically very low cost, convenience of self-administration, compactness and kind of easy manufacturing, contrary to popular belief. The most evident drawback of the commonly used oral dosage forms like tablets for all intents and purposes actually is difficulty in swallowing, leading to patient’s incompliance particularly in case of paediatric and geriatric patients, but it also applies to people who basically actually are usually ill in bed and to those definitely definitely active working patients who particularly kind of are busy or traveling, especially those who generally definitely have no access to water. To generally kind of fulfill those medical needs, fairly pharmaceutical technologists really basically have developed a novel oral dosage form known as Oral medicated jellies (OMJs) which disintegrate rapidly in saliva, usually in a matter of seconds, without the need of water in a subtle way. Drug dissolution and absorption as well as onset of clinical effect and drug bioavailability may actually kind of be significantly greater than those observed from conventional dosage forms.

Over a decade, the demand for development of oral medicated jellies (OMJs) specifically literally has enormously increased as it for all intents and purposes for
all intents and purposes has significant impact on the patient compliance, which basically essentially is quite significant. Oral medicated jellies for all intents and purposes are appreciated by a significant segment of populations particularly who particularly specifically have difficulty in swallowing, particularly contrary to popular belief. It for the most part has been basically essentially reported that Dysphagia (difficulty in swallowing) for the most part essentially is pretty common among all age groups and more kind of specific with paediatric, geriatric population along with institutionalized patients, psychiatric patients and patients with nausea, vomiting, and motion sickness complications, or so they actually literally thought. Common among all age groups, dysphagia mostly is observed in about 35% of the generally general population, as well as up to 60% of the sort of elderly institutionalized population and 18-22% of all patients in really fairly long-term care facilities. OMJs with kind of good taste and flavour increase the acceptability of bitter drugs by various groups of population, which specifically mostly is fairly significant.[3,4]

LITERATURE REVIEW

Shailaja Dombe et al./J.Pharm.Sci. & Res.Vol.11(6),2019- Herbal formulation of Brassica juncea -along with natural pomegranate syrup and carrageen as natural gelling agent was prepared. The prepared Oral medicated jellies have significant advantages of both solid and liquid dosage forms which were prepared by simple method using extract of Brassica juncea powder and pomegranate syrup. For all formulations, physical appearance, stickiness, pH, viscosity and In-vitro dissolution studies were assessed.

Kadam et al., IJPSR, 2020; Vol. 11(12)- Trazadone HCl antidepressant drugs incorporate in jelly and give to those patients; in this way, we could administer medicine to them without bringing this to their attention. Jellies are prepared by heating and congealing methods by dispersing gelling agents in water and evaluated for their physicochemical parameters like appearance, stickiness, pH, viscosity, Spreadability, stability studies, drug release, and content uniformity. All batches (F1-F8) of medicated jelly showed acceptable and comparable appearance, pH, viscosity, Spreadability, stability studies, drug release, and content uniformity.

Sarojini et al., WJPR, Vol 7,Issue 6- Oral medicated jellies as a dosage form can be adopted for drug delivery across buccal route, labial route, gingival route and sublingual route. Multiple drugs can also be incorporated in them for chronic illness treatments. Oral medicated jellies are available as the counter medications in different flavour based of mango, pineapple, strawberry, chocolate etc., containing drugs for anaesthetic, erectile dysfunction, arthritis, anti hypertensive, sore throat.

Sruthi Sunil et al., IPSR, Vol 12(7),2020- Chewable dosage forms are more convenient in administration of drugs for dysphagia patients and offers ease of handling compared to liquid and powder formulations. Chewable formulation has high drug carrying capacity and requires less amount of super disintegrants. Aesthetic appearance and pleasing taste of soft chewable system easily attracts children.

Ahire T. V. et al., [2016]- Have developed Albendazole oral jellies using suitable very natural and for all intents and purposes synthetic polymer as gelling agent with different concentrations, which kind of is fairly significant. Physical characteristics, pH, in vitro % drug release kinetics, content uniformity, spreadability, viscosity, IR spectral analysis, and stability studies were conducted in a really major way. The study really confirmed that the Albendazole oral jelly can essentially be used as a really possible alternative to recently available oral formulations.

Javalgikar A. et al., [2016]- Have prepared and evaluated Clotrimazole jellies for the treatment of candidiiasis using xanthan gum with different concentrations in a kind of major way. The sucrose based jellies generally were prepared by heating and congealing method in a subtle way. Physical characteristics, pH, syneresis, in vitro dissolution testing, drug release kinetics, IR Spectral analysis and stability studies specifically were conducted. IR spectroscopic studies basically indicated that there definitely were no drug-excipient interactions, actually contrary to popular belief.

Nayak K. et al., [2016]- Formulated oral definitely soft jelly of glibenclamide which literally is an orally administered anti-hyperglycaemic agent used in management of non-insulin dependent, (type-2) diabetes mellitus. Persons suffering from dysphagia may get chocked when they kind of consume for all intents and purposes liquid formulations, thus to for the most part alleviate very such problems really liquid formulations of basically high viscosity basically were prepared by using hydrophilic polymer guar gum at concentration ranging from 0.3-0.5% w/w and pectin at two different concentration (0.2% and 0.3% w/v), which literally is quite significant. The prepared batches really were evaluated for appearance, viscosity, pH, drug content, syneresis, and in vitro drug release.

Chhajed M. et al., [2012]- It basically had formulated unit moulded semisolid jelly for oral administration as a calcium supplement and optimization of this dosage form which will generally dissolve slowly when for the most part kept in contact with mouth without any irritation or inflammation and bitter taste, pretty contrary to popular belief. The formulation of jelly generally is advantageous for drug delivery in paediatric patient and may also generally be used in cases where tablet or capsule swallowing essentially is difficult, which particularly is quite significant. The jellies specifically were evaluated for their physicochemical parameters like colour, taste, loss on drying, pH, viscosity, spreadability, taste for...
Advantages of Jelly
1. It can specifically be administer easily i.e., anywhere, anytime as it basically is easy to definitely handle & doesn’t kind of require water in a fairly big way. Pretty therapeutic action of drug can kind of be terminated by spitting it before for all intents and purposes complete ingestion of medicated jelly.
2. It can also be used for systemic delivery of drugs, which essentially are particularly prone to metabolism in the gut wall or liver. Moreover, the drugs that particularly are liberated & swallowed from medicated jelly, will essentially reach the gastrointestinal tract either in dissolved or suspended form in saliva and hence it will for all intents and purposes be easily available.
3. Delivery of really therapeutic agent to systemic circulation through the oral mucosa can mostly help to for all intents and purposes overcome the problems related to difference in drug release and retention times in a subtle way.
4. It serves as for all intents and purposes ideal method of drug delivery for dysphasia patients as it reduces the risk of aspiration.
5. Basically pharmaceutical jellies can kind of be for all intents and purposes administer to the patients who cannot for the most part swallow tablets or capsules such as the elderly, stroke victims, bedridden patients, patients with for all intents and purposes oesophageal problems & patients who particularly refuse to swallow really such as paediatric, geriatric & psychiatric patients and thus improves patient compliance, or so they thought.
6. As saliva really pass down it actually facilitate rapid absorption of drugs through pre-gastric absorption from mouth, pharynx & oesophagus and increases bioavailability in a definitely major way.
7. Jelly is most convenient for disabled, bedridden patients, travellers and busy people, who do not always have access to water.
8. Good mouth feel property of jellies helps to change the perception of medication.
9. While administering conventional oral dosage form there is a chance of choking and by using jellies safety can be assured.
11. Suitable during traveling where water may not be available.
13. Cost effective.
14. Good chemical stability as conventional oral solid dosage form.
15. Allow high drug loading.
16. Provides rapid drug delivery from dosage forms.
17. Adaptable and amenable to existing processing and packaging machinery.
19. It is convenient to administer – anywhere, anytime, doesn’t require water.
20. The treatment can, if required, be terminated at any time.
21. It may prove to be particularly suitable for the systemic delivery of drugs, which are susceptible to metabolism in the gut wall or liver.\cite{5}

**Disadvantages**
1. As it mostly is aqueous based preparation it needs appropriate packaging to maintain stability of drugs in various environment.
2. It may literally lead to unpleasant taste if not formulated appropriately, which essentially is fairly significant.
3. Swallowing difficulties.
5. Lack of physical resistance in standard blister packages.
6. Cost intensive production process.\cite{5}

**TYPES OF JELLIES**

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 type 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.\cite{6}

**Challenges in Formulating Oral medicated jellies**

1. **Palatability**
   Masking taste of bitter drugs and enhancing taste directly related to patient compliance in aspirable way.

2. **Hygroscopicity**
   Some oral jelly dosage forms kind of are hygroscopic and they need protection from humidity so really needs specialized product packaging.

3. **Dose /Amount of drug**
   When the drug possess bitter taste, kind of more excipients should be particularly added to mask taste and this in turn increases the final size of dosage form.

4. **Aqueous solubility**
   Various excipients in jelly imparts crystallinity and rigidity for water soluble drugs which forms eutectic mixtures, which generally is fairly significant.

5. **Size of jelly**
   The degree of ease in taking a jelly depends on its size in a subtle way. It has been basically reported that the easiest size of jelly to swallow generally is 78mm while the easiest size to actually handle essentially was one larger than 8 mm in a subtle way. Therefore, the jelly size that generally is both easy to essentially take and basically easy to kind of handle essentially is difficult to achieve, which for the most part is quite significant.

6. **The Drug Property**
   Solubility, kind of crystal morphology, particle size and bulk density of a drug specifically affects the final jelly characteristics, or so they literally thought.

7. **Mouth feel**
   Medicated jellies literally leave minimal or no residue in mouth after oral administration, or so they thought.\cite{7,8}

8. **Sensitivity to environmental conditions**
   Oral medicated jellies generally should exhibit basically low sensitivity to environment conditions such as humidity and temperature as most of the materials used in an OMJ are meant to for the most part dissolve with minimum quantity of water in a pretty major way.\cite{9}

**Limitations of Oral Medicated Jellies**

1. Cost-intensive production process;
2. In a subtle way. Lack of actually physical resistance in standard blister packs;
3. Which specifically is quite significant. Oral medicated jellies requires special packaging for properly stabilization & safety of really stable product.
4. It specifically is also essentially shows the fragile, effervescence granules property, which really is quite significant.
5. Limited ability to incorporate higher concentrations of active drug.
6. ODT is hygroscopic in nature so must be keep in dry place.

**The Need for Development of Oral Medicated Jellies**

The need for non-invasive delivery systems persists sort of due to patients poor acceptance of and compliance with, existing delivery regimes, really limited market size for drug companies and drug uses, coupled with high cost of disease management in a subtle way.

**Patient factors**

Orally disintegrating dosage forms are particularly suitable for patients, who for one reason or the other, mostly find it inconvenient to swallow traditional tablets and capsules with an 8-oz glass of water, which definitely is fairly significant. These include the following-

1. Paediatric and geriatric patients who particularly have difficulty in swallowing or chewing generally solid dosage forms.
2. Patients who definitely are unwilling to mostly take definitely solid preparation due to fear of choking in a subtle way.
3. Very elderly patients who may not generally be able...
to actually swallow a daily dose of antidepressant in a subtle way.
4. An eight-year old with allergies who desires a definitely more convenient dosage form than antihistamine syrup, which literally is fairly significant.
5. A middle-aged woman undergoing radiation therapy for breast cancer may be too nauseous to definitely swallow her H2-blocker in a subtle way.
6. A definitely schizophrenic patient in an institutional setting who may particularly try to mostly hide a conventional tablet under his or her tongue to definitely avoid there for all intents and purposes daily dose of an atypical antipsychotic in a big way.
7. A patient with sort of persistent nausea, who may be journey, or has particularly little or no access to wate, contrary to popular belief.[11]

Drug Selection Criteria for Formulation

- Ability to permeate the oral mucosa in a major way.
- At hardly the least partially non-ionized at the oral cavity pH, which is fairly significant.
- Basically, Have the ability to really diffuse and partition into the epithelium of the upper GIT in a big way.
- Small to actually moderate molecular weight in a subtle way. Particularly low dose drugs preferably much less than 50 mg.
- Really short half-life and sort of frequent dosing drugs basically are unsuitable for OMJ in basically major way.
- Drug should have good stability in saliva and water, which for all intents and purposes is fairly significant.
- Very bitter or unacceptable taste and odour drugs are unsuitable for OMJ, very contrary to popular belief.
- Partially non ionized at the oral cavity's pH.
- Ability to basically diffuse and partition into the epithelium of the sort of upper actually GIT (log P > 1, or preferably >2).
- Ability to permeate oral sort of mucosal tissue in a major way. Drugs having ability to diffuse and partition into the epithelium of the actually upper for the most part GIT (log P > 1, or preferably > 2).
- Those able to permeate oral mucosal tissue essentially are considered kind of ideal for OMJ formulations in an actually big way.

Several factors must actually be considered when selecting drug candidates for delivery as OMJ dosage forms. In general, an OMJ really is formulated as a bioequivalent line extension of an existing oral dosage form, which kind of is fairly significant. Under this circumstance, if for all intents and purposes is assumed that the absorption of a drug molecule from the OMJ occurs in the post gastric literally GIT segments, similar to the actually conventional oral dosage form in an actually major way. But this scenario may not always specifically be the case, which is quite significant. An OMJ may have varying degrees of pre-gastric absorption and thus, the pharmacokinetic profile (including the kind of maximum plasma concentration, time to generally achieve maximal plasma concentration and area under the plasma concentration time curve of an equal dose of an OMJ and a conventional oral dosage form) willvary, or so they thought. Therefore, the OMJ will not literally be bioequivalent to the conventional oral dosage form in a big way. Examples mostly are cited in the literature in which the pharmacokinetic profiles and bio availabilities of the same dose of drug in an OMJ are not bioequivalent to the conventional oral dosage form, which essentially is quite significant. For example, OMJ formulations of selegiline, apomorphine and buspirone actually have significantly different pharmacokinetic profiles compared with the same dose administered in a conventional dosage form.

It basically is possible that these differences may, in part, particularly be mostly attributed to the drug molecule, formulation, or a combination of both. If significantly for all intents and purposes higher plasma levels have been observed, pregastric absorption leading to the avoidance of first-pass metabolism may generally play an important role. This situation may basically have implications for drug safety and efficacy, which may need to kind of be addressed and assessed in a marketing application for an OMJ, which is quite significant. For example, safety profiles may really be improved for drugs that specifically produce a significant amount of actually toxic metabolites mediated by first pass liver metabolism and gastric metabolism and for drugs that have a substantial fraction of absorption in the oral cavity and segments of the pregastric GIT, or so they really thought.

In contrast, the following characteristics may particularly render a drug unsuitable for delivery as OMJs.

Patients who concurrently really take anticholinergic medications may not be the definitely the best candidates for these drugs in a subtle way. Similarly, patients with Sjögren’s syndrome or dryness of the mouth actually due to essentially decreased saliva production may not be sort of good candidates for these tablet formulations. Drugs with a short half-life and pretty frequent dosing, drugs which are very bitter or otherwise unacceptable taste because taste masking cannot really be achieved or those which require controlled or sustained release for all intents and purposes are unsuitable candidates of rapidly dissolving oral dosage forms.

Researchers have formulated OMJ for various categories of drugs used for therapy in which rapid peak plasma concentration really is required to mostly achieve the desired pharmacological response, or so they thought. These particularly include neuroleptics, cardiovascular agents, analgesics, anti-allergic, anti-epileptics, anxiolytics, sedatives, hypnotics, diuretics, anti-parkinsonism agents, definitely anti-bacterial agents and drugs used for erectile dysfunction, which definitely is
Various Components of Medicated Jelly Formulations

<table>
<thead>
<tr>
<th>Gelling Agents</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Alginate</td>
<td>It is widely used as thickening agent and suspending agent in a various topical and oral pharmaceutical formulations such as pastes, creams and gels, also used in cosmetics and food products.</td>
</tr>
<tr>
<td>Gelatin</td>
<td>It is used as a biodegradable matrix material in an implantable delivery system. Gelatin is also widely used in food products and photographic emulsions.</td>
</tr>
<tr>
<td>Pectin</td>
<td>It is used as an adsorbent and bulk forming agent, experimentally it has been used in gel formulation for oral sustained delivery of drugs.</td>
</tr>
<tr>
<td>Tragacanth</td>
<td>In several pharmaceutical formulations, is used as an emulsifying and suspending agent. It is used in creams, gels, and emulsion formulations.</td>
</tr>
<tr>
<td>Xanthan Gum</td>
<td>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 has been used as thickening agent in shampoo.</td>
</tr>
<tr>
<td>Cellulose Derivatives</td>
<td>It is acting as a hydrophilic bulking agent and used to produce thermoplastic polymer. E.g. Methyl cellulosesodium carboxy methyl cellulose.</td>
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Preservatives

Since jellies for the most part are aqueous preparations which may definitely allow the microbes to grow, or so they essentially thought. Preservation must specifically be selected to really avoid any incompatibilities with the gelling agents, which may essentially retard the shelf life of the product. Cellulose derivatives and clay mostly resist the microbial attack, which mostly is fairly significant. Some examples of them literally are as follows: which for the mostpart is quite significant.

Methyl Paraben
Propyl Paraben
Benzoic acid
Benzalkonium chloride
Chlorhexidine acetate

Stabilizers

There are some additives that are added as stabilizers in the formulations to prevent the drying of jellies. Some examples of them are as follows:

Propylene glycol
Sorbitol
Chelating Agents: example- EDTA is added to prevent the sensitivity of bases and the medicaments toward heavy metal.[11,14]

Herbal Ingredients Used in Oral Medicated Jellies

- Glycyrrhiza glabra
- Spearmint

Glycyrrhiza glabra

Glycyrrhiza is one of the useful medicinal plants. Glycyrrhiza is derived from the ancient Greek term glykos, meaning sweet, and rhiza, meaning root. Glycyrrhiza glabra is known as mulaithi in north India. Glycyrrhiza glabra, also known as licorice and sweet wood, literally is basically native to the Mediterranean and very certain areas of Asia, contrary to popular belief. A number of traditional healers literally have claimed the efficacy of Glycyrrhiza species for a variety of pathological conditions as a diuretic, choleric, used as insecticide, and indicated in traditional medicine for coughs, colds, and painful swelling, sort of contrary to popular belief.

Scientific Classification
- Kingdom: Plantae
- Division: Angiospermae
- Class: Dicotyledoneae
- Order: Rosales
- Family: Leguminosae
- Genus: Glycyrrhiza
- Species: glabra Linn
- Binomial Name: Glycyrrhiza glabra Linn.
- Synonyms: Glycyrrhiza glandulifera
Glycyrrhizin Antiviral activity in phenols, genus Glycyrrhiza Linn is characterized by isoprenoid rapid spread as well as chronic infections caused by serious Multidrug accelerates basically of glycyrrhizin and helping to expel activities antitussive, demulcent, and expectorant loosening definitely major of basically sore throat, cough, and bronchial catarrh in a really. It for all intents and purposes has medicinal tinctures, Roots, Medicinal Parts Used. Roots and Rhizome (powder, teas, tonic, extracts, tinctures, decoction)

Pharmacological Activity
Antitussive and Expectorant The liquorice powder and kind of extract kind of was really found to for the most part be useful for the treatment of basically sore throat, cough, and bronchial catarrh in a definitely major way. It for all intents and purposes has antitussive, demulcent, and expectorant loosening activities which may attribute generally due to presence of glycyrrhizin and helping to expel congestion in the for all intents and purposes upper respiratory tract as it accelerates basically tracheal mucus secretion.

Antimicrobial
Multidrug-resistant microorganisms particularly pose a serious infestation in clinical medicine today due to the rapid spread as well as chronic infections caused by them, or so they really thought. Each species of the genus Glycyrrhiza Linn is characterized by isoprenoid phenols, which specifically have selective antimicrobial activity in a sort of major way.

Antiviral
Glycyrrhizin has a prominent antiviral activity, as it does not allow the virus cell binding.

Hepatoprotective Activity
Chronic hepatitis particularly (viral as well as nonviral) definitely is a slowly actually progressive liver disease that may generally evolve into cirrhosis with its generally potential complications of liver failure or hepatocellular carcinoma.

Spearmint
Spearmint, also known as garden mint, common mint, lamb mint and mackerel mint, is a species of mint, Mentha spicata, native to Europe and southern temperate Asia, extending from Ireland in the west to southern China in the east. It is naturalized in many other temperate parts of the world, including northern and southern Africa, North America and South America. It is used as a flavouring in food and herbal teas.

The aromatic oil, called oil of spearmint, is also used as a flavouring and sometimes as a scent.

Description
Spearmint is a perennial herbaceous plant. It is 30–100 cm (12–39 in) tall, with variably hairless to hairy stems and foliage, and a wide-spreading fleshy underground rhizome from which it grows. The leaves are 5–9 cm (2–3+1/2 in) long and 1.5–3 cm (1/2–1+1/4 in) broad, with a serrated margin. The stem is square-shaped, a defining characteristic of the mint family of herbs. Spearmint produces flowers in slender spikes, each flower pink or white in colour, 2.5–3 mm (0.098–0.118 in) long, and broad. Spearmint flowers in the summer (from July to September in the northern hemisphere), and has relatively large seeds, which measure 0.62–0.90 mm (0.024–0.035 in). The name ‘spear’ mint derives from the pointed leaf tips.
Taxonomy
Mentha spicata was first described scientifically by Carl Linnaeus in 1753. The epithet spicata means 'bearing a spike'. The species has two accepted subspecies, each of which has acquired a large number of synonyms:
1. Mentha spicata subsp. condensate (Briq.) Greuter & Burdet – eastern Mediterranean, from Italy to Egypt.
2. Mentha spicata subsp. spicata – distribution as for the species as a whole.

Origin and Hybrids
The plant is an allopolyplloid species (2n = 48), which could be a result of hybridization and chromosome doubling. Mentha longifolia and Mentha suaveolens (2n = 24) are likely to be the contributing diploid species. Mentha spicata hybridizes with other Mentha species, forming hybrids such as:
1. Mentha × piperita (hybrid with Mentha aquatica), black peppermint, hairy peppermint
2. Mentha × gracilis (hybrid with Mentha arvensis), Scotch spearmint
3. Mentha × villosa (hybrid with Mentha suaveolens)
   There are other cultivars:
   - Mentha spicata 'strawberry' - with a distinct strawberry odour.

History and Domestication
Mention of spearmint dates back to at least the 1st century AD, with references from naturalist Pliny and mentions in the Bible. Further records show descriptions of mint in ancient mythology. Findings of early versions of toothpaste using mint in the 14th century suggest widespread domestication by this point. It was introduced into England through the Romans by the 5th century, and the “Father of British Botany”, of the surname Turner, mentions mint as being good for the stomach. John Gerard’s Herbal (1597) states that: “It is good against watering eyes and all manner of break outs on the head and sores. It is applied with salt to the biting of mad dogs,” and that “They lay it on the stinging of wasps and bees with good success.” He also mentions that “the smell rejoice the heart of man”, for which because they used to strewit in chambers and places of recreation, pleasure and repose, where feasts and banquets are made.” Spearmint is documented as being an important cash crop in Connecticut during the period of the American Revolution, at which time mint teas were noted as being a popular drink due to them not being taxed.

Ecology
Spearmint can readily adapt to grow in various types of soil. Spearmint tends to thrive with plenty of organic material in full sun to part shade. The plant is also known to be found in moist habitats such as swamps or creeks, where the soil is sand or clay.

Spearmint ideally thrives in soils that are deep and well drained, moist, rich in nutrients and organic matter, and have a crumbly texture. pH range should be between 6.0 and 7.5.[20]

Uses
- Spearmint is used for digestive disorders including gas, indigestion, nausea, diarrhoea, upper gastrointestinal tract spasms, irritable bowel syndrome (IBS), bile duct and gallbladder swelling (inflammation), and gallstones.
- Good for digestive upsets.
- Mouth freshener.
- Antitussive.
- Rich in antioxidants.
- Aids women with hormonal imbalances.
- Improves memory.
- Fights bacterial infections.
- Lower blood sugar levels.
- May help reduce stress.
- Helps reduce arthritis pain.
- Lower blood pressure. [21]

MATERIAL AND METHOD

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Materials</th>
<th>Supplier/Marketer</th>
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<tbody>
<tr>
<td>1</td>
<td>Glycyrrhiza Glabra</td>
<td>Marketed by Schwabeindia</td>
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<tr>
<td>2</td>
<td>Spearmint</td>
<td>Marketed by Traditional Medicinals from iHerb</td>
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<tr>
<td>3</td>
<td>Disodium EDTA</td>
<td>PSGVPMs College of Pharmacy, Shahada</td>
</tr>
<tr>
<td>4</td>
<td>Propylene Glycol</td>
<td>PSGVPMs College of Pharmacy, Shahada</td>
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<td>5</td>
<td>Gelatin</td>
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<td>6</td>
<td>Sodium Alginate</td>
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<td>8</td>
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<tr>
<td>13</td>
<td>Distilled Water</td>
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Formula for Herbal OMJ

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<tr>
<th>Sr.No.</th>
<th>Ingredients</th>
<th>Formulation 1Qty(100g)</th>
<th>Formulation 2Qty(50g)</th>
<th>Formulation 3Qty(25g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Glycyrrhizaglabra</td>
<td>1</td>
<td>0.6</td>
<td>0.25</td>
</tr>
<tr>
<td>2</td>
<td>Spearmint</td>
<td>0.5</td>
<td>0.30</td>
<td>0.20</td>
</tr>
<tr>
<td>3</td>
<td>Disodium EDTA</td>
<td>0.1</td>
<td>0.05</td>
<td>0.052</td>
</tr>
<tr>
<td>4</td>
<td>Propylene glycol</td>
<td>3</td>
<td>1.3</td>
<td>0.8</td>
</tr>
<tr>
<td>5</td>
<td>Gelatine</td>
<td>15</td>
<td>9</td>
<td>4</td>
</tr>
<tr>
<td>6</td>
<td>Sodium Alginate</td>
<td>1.5</td>
<td>0.70</td>
<td>0.30</td>
</tr>
<tr>
<td>7</td>
<td>Citric acid</td>
<td>0.2</td>
<td>0.1</td>
<td>0.05</td>
</tr>
<tr>
<td>8</td>
<td>Methyl paraben</td>
<td>0.18</td>
<td>0.7</td>
<td>0.35</td>
</tr>
<tr>
<td>9</td>
<td>Propyl paraben</td>
<td>0.02</td>
<td>0.01</td>
<td>0.005</td>
</tr>
<tr>
<td>10</td>
<td>Simple syrup(60%)</td>
<td>60</td>
<td>35</td>
<td>18</td>
</tr>
<tr>
<td>11</td>
<td>Colouring agents</td>
<td>q.s.</td>
<td>q.s.</td>
<td>q.s.</td>
</tr>
<tr>
<td>12</td>
<td>Flavouring agents</td>
<td>q.s.</td>
<td>q.s.</td>
<td>q.s.</td>
</tr>
<tr>
<td>13</td>
<td>Distilled water</td>
<td>q.s.</td>
<td>q.s.</td>
<td>q.s.</td>
</tr>
</tbody>
</table>

**METHOD**

Oral 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 and propyl paraben 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, preservatives, colouring agents, flavouring agents with stirring. The final weight was adjusted with purified water, mixed and transferred to moulds and allowed to cool.[13]

**Evaluation of Oral Medicated Jellies**

a) **Physical evaluation**

The medicated jelly can be for the most part examined physically for appearance like clarity, texture, transparency, consistency in a for all intents and purposes major way.
b) **Stickiness and grittiness**
Texture of the medicated jelly in terms of stickiness and grittiness can specifically be determined by mildly rubbing the jelly between fingers.

c) **pH**
PH of jelly can particularly be measured using digital PH meter in a subtle way. 0.5 g of the weighed formulation mostly was dispersed in 50ml of water and the PH should basically be noted.

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

### Physio-chemical properties of oral soft jelly

<table>
<thead>
<tr>
<th>Sr.No.</th>
<th>Test Parameter</th>
<th>Formulation 1</th>
<th>Formulation 2</th>
<th>Formulation 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Clarity</td>
<td>T</td>
<td>T</td>
<td>T</td>
</tr>
<tr>
<td>2</td>
<td>Consistency</td>
<td>F</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>3</td>
<td>Texture</td>
<td>NG</td>
<td>NS, NG</td>
<td>NS, NG</td>
</tr>
<tr>
<td>4</td>
<td>Odour</td>
<td>P,F</td>
<td>P,F</td>
<td>P,F</td>
</tr>
<tr>
<td>5</td>
<td>pH</td>
<td>6.74 ±0.08</td>
<td>6.94 ± 0.08</td>
<td>6.98 ± 0.04</td>
</tr>
<tr>
<td>6</td>
<td>Viscosity</td>
<td>5790 ± 35</td>
<td>6548 ± 20</td>
<td>8161 ± 20</td>
</tr>
<tr>
<td>7</td>
<td>Syneresis</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

T: Transparent; F: Fluid; A: Acceptable; NS: Non sticky; NG: Non gritty; P: Pleasant; F: Fruity

e) **Syneresis**
Syneresis basically is defined as contraction and separation of water from gel upon storage. One of the very major causes for it is using pretty much lesser concentration of gelling agent, pretty contrary to popular belief. Low acylated guar gum gels are mostly prone to syneresis.

f) **Stability studies**
The jelly formulations kind of were packed in aluminium foils and stored in polyethylene containers at 0°C, 25°C/60%RH for 90 days.\(^{22}\)

### RESULT AND DISCUSSION

a) **General appearance**
All the batches of OMJs were transparent in appearance.

c) **Stability studies**
The results of short-term stability studies, indicated insignificant changes in pH, viscosity and appearance in the optimized formulation with time. Precipitation of drugs in the OMJs was notobserved in any of the jellies. Also, insignificant syneresis was not observed in any of the samples at both temperatures. Therefore, it is recommended that OMJs should be stored at about 25°C.

### DISCUSSION

It was found that the oral medicated jelly formulation 2 was substantially stable at both room temperature and also at low temperature, thus storage at room temperature is possible. Finally, it was found out Formulation 2 meets all laid in house specifications thus is the optimized formulation.

### SUMMARY AND CONCLUSION
Pharmaceuticals jellies for all intents and purposes have kind of aesthetic appearance and pleasant taste than any other oral drug delivery systems. It has fairly better organoleptic properties and patient compliance. It actually is can really be really administer anywhere and anytime without water. The drugs are released from jelly and swallowed, should particularly be introduced in the gastrointestinal tract either dissolved or suspended in saliva and hence it should specifically be generally present in a freely bioavailability form. Improve in patient compliance. Reduced dose frequency in a fairly major way.

Medicated jellies actually are feasible in kind of local treatment of disease of systemic conditions or oral cavity, sort of contrary to popular belief.

The formulation particularly is one of the novel approach, definitely aims to actually improve safety and efficacy. For the preparation of formulations, pretty several gelling agents and excipients kind of are to for all intents and purposes be used and sugar syrup should be used assweetness or improvement in the acceptable taste, which particularly are mostly accepted by children in generally current period as jelly candies.

To be concluded that prepared medicated jelly is more organoleptically accepted particularly by patients with disability in ingestion of food and drink, in other words, those having difficulty in mastication and swallowing. Prepared medicated jelly is cost wise cheap and acceptable and have gained relevance in pharmaceutical industry as a novel, patient friendly, convenient products.\(^{23}\)

### ACKNOWLEDGEMENT
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We take opportunity to convey our intentness to all those who directly or indirectly contributed to successfully completion of our project.

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