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To study of of domperidone and ondansetron medicated jelly formulation

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Abstract
The objective of this investigation was to developed and assess and oral jelly containing domperidone and ondansetron for addressing nausea and vomiting in pediatric patients. Through the application of heating and congealing method,specific proportions of active compounds and additives were integrated into the jelly formulation. Preformulation examinations were conducted to evaluate both the physical and chemical characteristics,while the evaluation criteria encompassed various aspects such as the appearance, texture, spreadiability, viscosity, ph level, uniformity of content, *in vitro* dissolution and stability over a three month period. Findings indicated favorable physical attributes, consistant drug content, suitable ph levels, non-adhesive texture, excellent spreadability, appropriate rheological properties, efficient drug release and stability without notable alteration in appearance, ph or drug content over the disignated time frame. Overall, the developed medicated jelly demonstrated promosing qualities for pediatric application, suggesting it's potential as a dependable and safe oral dosage for managing nausea and vomiting in children.

Keywords: Medicated jelly, domperidone, ondesterone, nutraceuticals, gelatin, carbapol 934.

Introduction
According to the Japanese pharmacopeia (JP XVII), jellies are described as non-flowable gelatinous formulations design for oral intake, characterized by specific shapes and dimentions [1] despite notable progress in drug delivery methods, oral administration remains preferred route for delivering therapeutic substances. These preference persites due to it's simplicity of use and it's ability to promote adherness, largely atribhuted to it's cost-effectiveness in therapy.

it's also thought to be the least expensive and safest way provide medication. There are various preparations available for drug delivery orally, including tablets, pills, capsules, syrups and more. Patients who are young and occasionally elderly, especially those who have dysphegia, find it difficult to consume these dosage forms. But when formulating into dosage forms, there are challenges due to liquid, include hiding the bitterness of the active ingredients, theirdispersibility, and their stability. Depending on their size, pediatrics have difficulty swallowing pills or capsules.

However, there are the lot of issues with using that kind of formulation in pediatrics, including stability, dosage waste, dose dumping, and so on. In addition, kinds don't seem interested in taking this kind of formulation. Consequently, the goal has been to create novel pharmaceutical formulation that are simple for pediatric and dysphagic patients to take. There are several oral dosage forms pediatric formulations, including syrup, suspension, dry syrup, and others.

The oral cavity absorbs a large number of therapeutic agent. Chewing gums and medicated jelly are two dosage forms thet allow for a faster therapeutic effect than oral dosage forms for drugs with significant buccalabsorbtion [2]. Medicated jellies have numerous benefits over traditionaldosage forms. They are soft and smooth,making them easy for both adults and children toingest. Children also prefer jelly over tablet dosage forms because of their attractive appearance.

Medicated jellies can be used to treat oral infection and systemic diseases as well as xerostomia [3]. Since the most frequent issue dysphagic patients encounter when using traditional dosage forms is choking,

medicated jelly may be a preferable substitute [4] when using bitter-tasting medication, high dosage can cause discomfort for the patient. The taste of the medication in high-dosage formulations cannot be concealed by coating granules, tablets, or by creating microcapsules, due to the possibility of irritation from the coated medication coming into contact with the oral cavity, the pharynx may experience difficulty swallowing. Carragenan, pectin, agar, sodium alginate, and gelatin are a few of the gelling agents used to prepare jelly. Only with pectin medication that are stable in acidic environments be made into jelly [5] peripheral dopamine 2-receptor antagonist include domperidone [6] the GI DA2-receptor mediate the predominant inhibitory effects of dopamine on smooth muscle by interacting with the cholinergic system [7-9]. Domperidone has direct antiemetic effects that are not observed with cisapride because of it's activity at DA2-receptor in the chemoreceptor trigger zone (CTZ) [10-12].

The racemic form of ondansetron, ondansetron hydrochloride, selectively blocks the 5-HT3 receptor type of serotonin, 5-HT 3 receptor are found centrally in the brains postrema region and peripherally on vagal terminals. It's unclear if ondansetron acts through a peripheral, cetral, or combined mechanism. Serotonin is released from the enterochromaffin cells of the gastrointestinal tract as a result of cytotoxic drug and radiation-induced mucosal damage. When 5-HT 3 receptor are stimulated, sensory signals are via vagal afferent fiberes to the vomiting center, where they are translated into vomiting. ondansetron inhibits serotonin-mediated vomiting by attaching to 5HT 3 receptors [13].

Ondansetron and domperidone are only sporadically soluble in water. It efficiently absorbs viathe oral cavity [14]. The optimized complex is prepared as a jelly and assessed based on a number of factors, including dissolution, weight variation, ph, syneresis, and physical appearance. Hence, the present work is development and evaluation of oral medicated jelly for the treatment of nausea and vomiting specially in children.

Fig 1: Medicated jelly

Literature review

Raja Manali M *et al.* despite significant advancement in drug delivery systems, the oral route remains the preferred method for administering therapeutic agents due to its cost-effectiveness and ease of use, promoting patient adherence. One oral innovative formulation gaining attention is medicated jelly, particularly suitable for elderly patients and those with swallowing difficulties. This unique jelly can be chewed easily and dissolve in saliva, acceptance, thus improving compliance. This article outlines essential components, preparation techniques, and evaluation criteria for oral jelly formulations [2].

Jadhav S.B *et al.* the objective of this study was to develop and assess the effectiveness of oral medicated jelly containing ondansetron HCL for managing nausea and vomiting. Jellies characterized by their semi-solid top thick viscosity, offer a convenient optiuon for individuals with advanced age ar difficulties in swallowing and masticatrion. These medicated jellies offer several advantages, including enhanced bioavailablity due to bypassing first-pass metabolism, ease of consumption without water, and improved acceptance among pediatric patients. The preparation method involves heating and congealing, where in gelling agents are dispersed in water. The formulated jellies were subjected to comprehensive evaluation, including assessments of appearance, stickiness, ph, viscosity, spreadability, stability, drug release kinetics, and content uniformity. All batches (designated as F1 to F2) exhibited satisfactory results across these parameters. The viscocity ranged from 619007 to 710077 cps, whiloe the drug content of formulations F1 to F12 fell within the range of 95.21% to 103.76%. notably, batch F8, formulated with xanthan gum, demonstrated a drug release of 101.04% (15).

Mahendra kumar dubey *et al.* the primary objective of this investigation was to develop and assess unit molded medicated jelly containing palonosetron hydrochloride for managing nausea and vomiting induced by chemotherapy and radiation therapy. Jellies, characterized by their semi-solid to thick viscosity, offer a convenient option for individuals, particularly those of advanced age or with difficulties in as allowing and mastication. This dosage form can be ingested without water and possesses a soft and smooth texture, enhancing ease of consumption. The formulated medicated jellies underwent through evaluation for various physicochemical parameter including appearance, stickiness, ph, viscosity, drug release, kinetics, and content uniformity. Across all batches (designed as F1 to nF12), the jellies exhibited acceptable and comparable characteristics in term of appearance and ph. The viscosity ranged between 536000 to 636000 cps, while the drug content of formulation F1 to F12 fell within the range of 97.26%. Notably, formulation F8 demonstreted a drug release of 100.03% [16].

Doolaanea AA *et al.* oral jellies represent a category of non flowablr gelatinous preparations charactzed by their specific shape and dimentions. Researchers are increasingly investigating the potential of this dosage form for diver's populations, including pediatric, geriatric, and dysphagic patients. Compared to liquid formulations, jellies offer various advanntag3es such as enhanced palatability, improved patient acceptance, suitability for controlled release applications, and stability. However, despite these advantages, there remains a dearth of comprehensive information regarding various aspects of jelly formulation tailored for pediatric use. Therefore, further vextensive studies are encouraged to fill this knowledge gap and optimize the application of oral jellies in pediatric medicine [17].

Paras B. Pophalkar *et al.* the primary goel of this research is to develop a medicated jelly formulation of ondensetron tailored for effective administration in pediatric patients. Ondensetron belong to a novel class of antiem, etic drugs initially designed to manage chemotherapy/radiotherapy-induced vomiting, later proving effective in postoperative

nauseaand vomiting as well. Its mechanism involves blocking the depolarizing action 5-HT through 5-HT3 receptors, primarily located on vagal afferents in the gastrointestinal tract, as well as in the nucleus tractussolitsrius 9NTS) and the chemoreceptor trigger zone (CTZ). Compared to liquid formulations, medicated jelly presents more convient option for pediatric administration. This formulation not only serves as a promising alternative for drug delivery in pediatric, geriatric, and dysphagic patients but also offers significant advantages over both solid and liquid dosage fprms. Its solid state during storage ensures stability, while its rapid transformation into a liquid-like form upon administration facilitates ease of intake. The medicated jelly formulation, comprising gelling agents such as gelatin and corbopol 934, along with other excipients and sugar syrup, underwent in-vitro dissolution testing to assess ondensetron release. Among the formulation tested, F3 emerged as the optimal choice based on dissolution profile analysis. F3, formulated with gelatin as the gelling agent, exhibited non-sticky properties compared to carbopol 934, thus minimizing weight variation and enhancing dissolution efficacy [18].

Mukati S. *et al.* the objective of this research was to explore the potential of combining ondansetron and domperidone in a single medicated gum formulation. Molded chewing gum (MCG) was developed using direct compression method, with a focus on creating a product suitable for individuals with diabetes. Stevia was chosen as the sweeterner due to its non-impact on blood glucose levels. Various pre-compression parameter including bulk desity, tapered density, carr's compressibility index, and hausner ration were evaluate for each formulation to ensure permissible flow characteristics. Post-compression analysis indicated that all parameter fell within acceptable limits, including changes in weight, thickness, appearance, and *in vitro* drug release. Physical testing and TLC analysis revealed no evidence of drug-exipients interaction. Comparative analysis between glycerol and coconut oil as plastisizer showed coconut oil to be superior. Formulation F6 was identified as the optimal choice, meeting all expected attributes. Further evaluation of F6 demonstrated consistent thickness, minimal weight fluctuation, desirable appearance, and satisfactory *in vitro* drug release. Coconut oil emerged as the preferred plastisizer due to its optimized concentration for drug release within the formulation. The inclusion of 24 mg of coconut oil in F6 contributed to its effectiveness [19].

Ruheenataranum *et al.* the development of oral medicated jelly represent a significant advancement in drug delivery, particularly catering to the needs of pediatric and geriatric offers a solution for individuals with swallowing difficulties, as it can be easily chewed and dissolves effortlessly in saliva without the requirement of water for ingestion, dishtingguishing it from other forms. Moreover, its appealing appearance and soft texture contribute to its high acceptance among patients. In this study, a domperidone jelly formulation was developed to provide rapid relief from nausea and vomiting compared to traditional dosage forms. The formulation comprised sucrse, gelatin, citric acid, sodium citrate, and sodium benzoate, prepared using the heating and congealing method. Comprehensive evaluation including appearance, weight variation, ph, syneresis, drug content, and dissolution were conducted. The optimized formulation exhibited a remarkable drug release of 98.39%within 25 mintes. Comparative analysis with a soft chew formulation (F9) revealed thatr the medicated jelly (F5) demonstrated superior drug release efficacy. Stability studies conducted in accordance with ICH fuidlines confirmed the acceptable stability of the optimized form,ulation (F5), further validating its potential as an effective drug dekivery system [20].

Jiang-hong ye *et al.* ondensetron, a selective 5-hydroxytryptamine3 (5-HT3) receptor antagonist, has emerged as pivotal medication in clinical practice for managing nausea and vomiting induced by cancer treatments and anesthesia.it's dual prophylactic and therapeutic roles have been well-established, showcasing superior efficacy, safety, and economic benefits compared to alternative antiemetics such as antidopaminergics, antihistamines, and anticholinergics. Despite its recognized efficacy, there remains a scope for further exploration of ondensetron's role in managing anticipatory and delayed vomiting during cancer treatment, as well as it's potential as a rescue antiemetic in surgical settings. Recent research in both animalmodels and human subject has unveiled promising novel application of ondansetron in diverse disease states, including alcoholism, cocaine addiction,opioid withdrawal syndrome, anxiety disorders, gastrointestinal motility disorders, tourette's syndrome, and pruritus. This review delves into the extensive physiological and pathological impacts of serotonin (5-HT), elucidating the foundamental scientific literature and clinical advancement that have paved the way for conventional and emerging uses of ondansetron. Furthermore, in highlights recent discoveries concerning ondansetron's effects on additional receptors and channel, along with their potential therapeutic implications [21].

Chudamaniyadav *et al.* in contempory pharmaceutical advancement, the oral route remains the preferred method for drug administration due to it's convenience and enhanced therapeutic benefits, promoting patient adherence to treatment. In recent times, jelly candies have gained popularity among children with complete dentition due to their appealing taste and chewable texture, often infused with fruits flavors. This trend is particularly beneficial for patient with dysphagia, as traditional liquid formulation with high viscodity can pose risks of chocking, necessitating the development of alternative pharmaceutical preparations. One such innovative approach is the development of oral medicated jelly, aiming to enhance safety and efficacy. These formulation are readily accepted by patient with dysphagia, as well as pediatric and geriatric patients, thereby improving patient compliance compared to conventional dosage forms. This review aims to provide a concise overview of the advantages and disadvantages of oral medicated jelly, including the types of gelling agents and exipients used, methods of preparation, evaluation parameter, and it's significance over conventional drug forms [22].

S. Sarojini *et al.* oral medicated jellies have a rich history dating back to the 20th century and continue to enjoy popularity among consumers, leading to their sustained commercial production. These palatable solid dosage form are designed for administration in the oral cavity, intended to dissolves in the mouth ir pharynx for local or systemic effects. While oral medicated jellies offer numerous advantages as pharmaceutical formulations, they also present some drawbacks. This versatile dosage form can be utilized for drug delivery through various routes such as

buccal, labial, gingival, and sublingual. It allows for the incorporation of multiple drugs, making it suitable for chronic illness treatments. Available over the counter, these jellies come in the range of flavours including Mango, pineapple, strawbwrry, and chocholate, containing drugs for divers conditions such as anaesthetics, erectile dysfunction, arthritis antihypertensive, and sore throat, A significant milestone occurred in 2012 when the ministery of health,labour and welfare of japan approved the world's first once-weekly oral medicated jelly for osteoporosis treatment. This underscores the widespread acceptance of oral medicated jellies in the international market, particularly for addressing both male and female sexual dysfunction. This review delves into various aspects of oral medicated jelly formulation, offering valuableninsight to formulation scientists regarding the novel application of this versatile drug delivery system [23].

Aim: To develop an oral jelly formulation containing domperidone and ondansetron tailored specifically for pediatric, addressing the challenges of vomiting management in this demographic.

Objective: Develop an oral jelly formulation incorporating domperidone and ondansetron, specifically tailored to address nausea and vomiting in pediatric patients.

Jeliies: Jellies are translucent, transparent or non-greasy semisolid preparation meant for external and internal application natural gelling agent such as pectin, sodium alginate or from synthetic derivative of substance such as methyl cellulose and sodium carboxymethyl cellulose for the preparation of jellies [24].

Development of oral medicated jelly formulation are more suitable for pediatric, geriatric and patients with dysphagia. The patient with dysphagia should be choked with during taking liquid formulation, hence this problem should be shortcut by administering liquid formulation having high viscosity in the form of jellies [25, 26].

Jelly formulation have been developed that aim to enhance patient compliance by aiding swallowing [27, 28]. Different gelling agents usually employed are tragacanth, sodium alginate, pectin, starch, gelatin; cellulose derivative such as hydroxypropyl methyl cellulose, methylcellulose, carbomers, polyvinyl pyrrolidone and polyvinyl alcohol using various additives at different concentration [29, 30]. Commercial oral jelly product of calcium gluconate, metformin hydrochloride, amlodipine, acyclovir, alendronate, donepenzil hydrochloride, sildenafil and available in some countries but scarcely any product found in those patient who really need them [31, 32].

Medicated jelly is is mainly use in the case of local treatment or in systemic condition [33, 34].

Types of jellies

Several types of jellies are as follows;

Medicated jelly

These types of jellies contain sufficient water which are mostly used on skin and mucous membrane for their spermicidal, local anaesthetics and antiseptics properties. It gives a local cooling sensation and applied film gives protection after evaporation of water. For example ephedrinesulphate jelly is used for vasconstrictor 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. [35].

Material and method

Material:

Table 1: Ingredients and quantities for ondansetron-domperidone formulation per 100g

Sr. No	Ingredients	Quality (gm)
1	Drug (ondansetron and domperidone)	0.719
2	sucrose	50
3	Xanthum gum	6.66
4	gelatin	1.66
5	Citric acid	0.166
6	Sodium citrate	0.833
7	Sodium benzoate	0.99
8	Water	QS
9	Colour	QS
10	Flavor	QS
	Total	**100gm**

Method

1. In the preparation of medicated jelly, precise measurements of the required ingredients are crucial for consistency and effectiveness.
2. The process begins by accurately weighing all the necessary components as outlined in the formulation.
3. To create the sucrose syrup, sucrose is added to water in the specified quantities as indicated in Table 1. The mixture is then heated until the sucrose completely dissolves. To prevent crystallization, citric acid is incorporated into the syrup.
4. Gelatine, a key component, is soaked in the appropriate amount of water to promote hydration. Once hydrated, it is introduced into the sucrose syrup mixture and heated until fully dissolved.
5. Following the dissolution of gelatin, additional components such as Domperidone complex, Ondansetron and sodium benzoate are dissolved in a suitable vehicle. This solution is then added to the main mixture while stirring continuously to ensure uniform distribution.
6. Sodium citrate is subsequently introduced into the mixture to regulate pH levels, maintaining the desired balance.
7. To enhance the visual appeal and taste, coloring and flavoring agents are incorporated into the mixture. Thorough mixing ensures even distribution of these additives.
8. Throughout the preparation process, the weight of the jelly is closely monitored to ensure consistency. Adjustments are made as necessary to achieve the desired final weight of 100g, using distilled water if needed.

9. Once the desired weight is attained, the mixture is transferred into molds and allowed to cool until it solidifies into jelly form.
10. The finalized jelly is then carefully packed using gelatin paper to maintain its integrity and stored in a dry environment to prevent moisture-induced degradation. This methodical approach to preparing medicated jelly ensures reproducibility and quality control, essential aspects for research and pharmaceutical applications.

Fig 2: Some photographs of jellies formulation

Evaluation parameter

Physical appearance

Insuring patients comfort and satisfaction lies at the core of effective healthcare, and physical examination are piotal in achieving thise goal. Employing a personaliezed approach we conduct meticulous assessment of the prepared jellies, scrutinizing them for coulor texture and clarity with gret attention to detail. Thise hand on examination gurantee a comprehensive understanding of the substance in question, fostering a rhouthful and through evaluation process.

Stickiness and grittiness: To grap the stickiness, adopt a hands-on approach to the assessment. Hold the jelly sample and softly rub it between your fingers while visually examine the formulation. This tactile inspection offers a personal connection, enabling a nuanced comprehention of the product's texture and attributes.

Table 2: Evaluation of clarity, color, odor, particulate matter, and stickiness

Sr.no	Test parameter	T1	T2	T3	T4	T5
1	Clarity	Clear	Clear	Clear	Clear	Clear
2	Colour	Orange	Orange	Orange	Orange	Orange
3	Odour	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant
4	Particulate matter	None	None	None	None	None
5	stickness	slight	slight	slight	Not significant	Not significant

Table 3: Stickiness evaluation across five tests with varying consistency results."

Test performed	T1	T2	T3	T4	T5
stickiness	Non-sticky	Non-sticky	Slightly sticky	Slightly sticky	sticky

Ph: the ph of the jellies was assessed using a digital ph meter at room tempreture. To do this, 0.5 g of jelly was mixed in 50 ml of distilled water to create a 1% solution, and the ph was recorded. The ph of the final jelly not only affects its stability but also influence its taste.

When it comes to the pourability of the mixture, ensuring that it flows smoothly into the molds is essential. Buffer salts, such as trisodium citrate, play a crucial role in this process. During the heating phase, they form a protective barrier around pectin molecules through steric inference, preventing premature gel formation before the introduction of acid, the concentration buffer salt lowers the setting tempreture and extends the setting time, providing ample opportunity for the jelly to be poured into moulds and set properly. This process allows the jelly to gracefully take its time to set and transform into the delightful treat we all enjoy.

Table 4: pH measurement across five tests with minimal variation observed

parameter	T1	T2	T3	T4	T5
pH	6.82±0.05	6.81±0.05	6.86±0.05	6.82±0.07	6.81±0.005

Taste evaluation

Volunteers eagerly participated in the enjoyable task of taste evaluation. They presented our esteemed taste panel experts with a delighfulnfive-gram portion of the optimize formulation, encouraging them to savor the gel for a brief yet pleasurable five seconds. With tste buds poised, the experts were warmly welcomed to share their impression and feedback on the flavor experience.it is through these personal interaction tastw the genuine essence of taste truly blossom.

Viscocity study

The viscosity of the jelly was determined using a fungilab viscometer, utilizing non-newtonian spindle no. 4. The measurmemnt was conducted for a fixed duration of 2 minutes at a speed of 1.5 rpm at a tempreture range of $250^0C + 50^0C$.

Texture analysis

Imagine gently pressing your fingers onto the smooth surface of the gel. In our testing methodology, we've adopted a similar tacticle approach. Instead of using fingers, we employ a specialized hemispherical probe, approximately 12mm in diameter, meticously crafted to mimic the natural touch and movement of pressing fingers into the sample into the sample. This probe is not merely a tool; it's intricately linked to a load cell. Acting as a sensitive observer, the load cell measures and comprehends how the sample react as the probe penetrates. It's akin to engagimg in a dialogue with the gel, deciphering it's behavior, and ensuring that every interaction yields meaningful insights in our pursuit of accurate and insightful analysis.

Content uniformity

Picture this process as a culinary adventure: We meticulously collected samples of jelly from each distinct formulation, treating them with the same attention one would devote to selecting ingredients for flawless recipe. After gently crushing and blending these components, we extracted the equivalent drug content using a method akin to crafting a special sauce-just right. To delve into the essence of these blends, we ventured beyound taste alone. Envision a scientific chef meticulously measuring the precise elements in a dish. We utilized a uv-visible spectrophotometer to assess the absorbance of eachsolution at the optimal wavelength or employed a method as refined as a seasonal cook's technique. Why such precision? It's akin to ensuring every slice of cake boasts the same sweetness. This comprehensive test is our assurance that each dosage form in the batch mirrors the others, containing an identical amount of active pharmaceutical ingredients. It's not solely about uniformity; it's about crafting a dependable blend, a pharmaceutical masterpiece you can rely on with every dose.

Table 5: Drug content analysis shows consistent results across five test conditions

condition	T1	T2	T3	T4	T5
Drug content%	99.29±0.02	99.32±0.05	99.52±0.071	99.79±0.09	99.26±0.062

***In-vitro* dissolution study**

Envision our in-vitro dissolution study as a meticulously coordinated performance. We opted for a USP paddle-type apparatus, much like selecting the appropriate instrument for a musical piece. And positioned it in a warm environment set at show. As time progressed in intervals of 10, 20, 30, 40, 50, 60, 90, and 120 minutes, we carefully withdrew 5 ml of the sample, treating it with the precision of a seasoned chef crafting a delicate dish. Each withdrawal was an act of precision, as we diluted the sample to 10 ml in a flask, maintaining balance, much like composing a harmonious melody. Sink condition were diligently maintained throughout our performance. With each sample withdrawel, we replenished it with fresh media, ensuring the stage was set for the next act. Following this meticulous choreography, our focus shifted to evaluating the drug content in the samples, akin to savoring the distinct flavor in a blend.utilizing a uv-spectophotometer or a suitable analytical method, we captured absorbance readings that facilitated the calculation of the percentage of the drug release. This methodical approach represents our endeavor to unravel the drug's narrative over time, infusing depth and significance into the overall efficacy of our study-a symphony of science and precision.

Spreadability

Picture the jelly as an awaiting canvas ready to unveil its enhancement. With precision, we positioned 2.5 grams between two glass slides, applying just enough pressure to achieve the desired thickness. A delicate 1000-gram weight added our artistic touch, resting upon this creation for 5 minutes. As if allowing the jelly a movement to settle and find its cadence, we witnessed the unfolding masterpiece. The brief seconds it took for the two slides to gracefully part ways severe as our measure of spredability-a glimpse into the seamless interplay of ingredients. In our quest foe exllence, we aimed for a shorter time interval to cover a distance of 7.5 cm, symbolizing the essence of superior spreadability. It's not merely about figures; it's about ensuring that each spread narrates a tale of smoothness and excellence, crafting an experience that transcends mere calculation.

Syneresis

As we employ a limited concentration of the gelling agent, this interplay becomes more apparent, particularly within the realm of gels. We assume the role of attentive observes, safeguarding this delicate ballet. In our cozy laboratory environment, we meticulously monitored each jelly, akin to caretakers tending to a garden. At room tempreture (25ºC ± 5ºC) and a slightly cooler 8ºC ± 1ºC, we patiently awaited signs of this natural separation, know5%n as syneresis. It's as though we were nurturing thr well-being of the gel, much like a viligiant gardener. And like discerning gardenes, if any formulation hinted at signs of syneresis, we made a careful decision-not to pusue further studies with these. It's reminiscent is not merely good, but truly exceptional.

Stability studies

In accordance with ICH guidelines, the study necessitates placing the samples at various tempreture (ranging from 0-8ºC) and at room tempreture for a duration of 3 months. The jelly samples should be assessed for viscosity, appearance, and ph at monthly intervals. All measurements were conducted after allowing the samples to equilibrate at 25ºC for 2 hours. Additionally, environmental conditions of 25ºC with 60% RH (±2ºC/±5%RH) and 30ºC with 65% RH (±2ºC/±5% RH) were maintained during the study.

Table 6: Stability study results: appearance, pH, and drug content consistency

Sample Id	Duration of stability study	Appearance observation	Synergy insights	pH range	Drug content percentage
1	4 week	No change observed	None	6.85±0.05	99.29±0.02
2	8 week	Unchanged appearance	No significant synergies detected	6.85±0.35	99.28±0.02
3	12 week	Appearance reains stable	Absence of notable synergies	6.85±0.03	99.19±0.03

Advantages

1. It is can be administer anywere and anytime without water.
2. The treatment can be terminated easily at any time if required.
3. The drugs are released from jelly and swallowed, should be introduced in the gastrointestinal tract either dissolved or suspended in saliva and should be present in a freely bioavailablity from.
4. It has the potential to overcome the problem of short lived action and variation on drug release and retention times via the oral mucosa [36].
5. Flexibility in design.
6. Improved in patient compliance.
7. Reduced dose frequency.
8. Medicated jellies are feasible in local treatment of disease of systemic condition or oral cavity.
9. Highly acceptable by children, elderly and dysphagic patient.
10. Excellent or acute medication.
11. Easily manufacturing and lower cost.
12. Easily produced elegant and stable.

Disadvantages

1. It is aqueous preparation hence it needed proper packaging for stabilization and safety of drugs.
2. It may produce unpleasant taste in mouth if not formulation properly.
3. Due to presence of sorbitol or sucrose in medicated jelly can flatulence and diarrhea [37].
4. Jellies compared to liquid formulation:
5. Pediatric oral formulation can be scientifically challenging to develop the prerequisites for bothb a measurable dosage form based upon bodyweight and taste-masking are two of the chanllenges unique for pediatric oral formulation the majority of active pharmaceutical ingredients (APIs) found in oral dosage form have bitter taste [38].
6. Taste masking of liquid formulation presents a major chanllge because most of pediatric preparation are syrup and commercial success for the quality of treatment provided to suffering patients, especially children (39).pediatric population cover the age from birth up to age 16 or 18 this population can be subdivided according to the documents from European medicine agency (EMEA) as following [40].

- Preterm newborn infants.
- Term newborn infants (0-27).
- Infants and toddliers 91 month to 23 months)
- Childrens (2-11 years) : could be further subdivided in terms of the childs ability to accept and use different dosage form, e.g. into preschool children (92-5 years) and school children (6-11 years)
- Adolescents (12-16 or 18 years).

The physicochemical and oragoleptic properties of the active drug substance such as solubility, chemically stability and taste along with the intended dose can determine which formulation are feasible to develope strictly [41].

Reported that oral pediatric formulations are available in 17 different varieties and can be either; ready-to-use formulation such as a;

1. solution
2. syrup
3. suspension
4. tablet
5. scored tablet
6. chewable tablet
7. orally disintegrating tablet or
8. thin strip or formulation that require manipulation such as a
9. powder for constitution to a suspension
10. tablet for constitution to a suspension
11. powder for constitution to a solution
12. drops for reconstitution to a suspension
13. concentrated solution for dilution
14. effervescent tablet
15. bulk oral granules
16. bulk oral powder
17. solid in a capsule to mix with food or drink

According to our search no new pediatric dosage form was commercialized other than those reported in the previous study. A careful view on the 17 dosage form leads to a conclude that the final dosage form that the pediatric will administer (after reconstitution) can be classified into;

Liquid dosage from

Solution, syrup, suspension, powder for constitution to a suspension, tablet for constitution to a suspension, powder for constitution to a solution, drop for reconstitution to a suspension concentrated solution for dilution, effervescent tablet.

Solid dosge form

Tablet, scored tablet, chewable tablet, orally disintegrating tablet, thin strip, bulk oral granules, bulk oral powder and solid in a capsule to mix with food or drink.

A major concern is at what age children can safely swallow solid dosage form such as tablet or capsule again, this is generally a factor of age and health status but there are significant inter-patient differences around an average of about 6 years taste, smell and texture will be important factors for any repeated administration of medicinal products, which are uncomfortable, painful or stressful [42].

It is estimated that 50% of the population have problem of swallowing tablets especially the pediatric and geriatric population [43].

Current pediatric dosage form have several drawbacks especially for the age below 6 years the ideal pediatric formulation needs to consider the following crititeria as suggested by European medicines agency

- Minimal dosage frequency
- One dosage form fits all or a full range
- Minimal impact on life style
- Minimum non - toxic excipients
- Convenient, easy, reliable administration
- Easily produced, elegant administration
- Cost and commercial

Current liquid dosage form provide several advantage such as dose flexibility and ease of swallowing in fact they are the most appropriate for younger prdiatric patients however, liquid dosage forms have several disadvantages, among them.

- The dose volume is a major consideration
- Less than 5 ml for children under 5 years
- Less than 10 ml or children of 5 years and older
- Stability issues; the drug is beign in solution or suspension form and hence easier for degradation.

- Patient acceptability; since the durg is completely or partially dissolved it will be in direct contact with the taste sensors in the tongue. This introduces challengs in taste masking and requires high sugar or sweetener concentration to be used.
- Challenging controlled release; only few sustained release liquid formulation are available in the market.
- Higher transportation costs; due to the large weight of the product.

Conclusion

In conclusion the developed oral jelly formulation containing domperidone and ondansetron demonstrates promising qualities for pediatric application in manaing nausea and vomiting the comprehensive evaluation of various parameters indicates its suitability and reliability, highlighting its potential as an effective and convenient oral dosage form for pediatric patients. Further studies and clinical trials may validate its efficacy and safety, ultimately contributing to improved healthcare outcomes for children experiencing nausea and vomiting.

The study reveals that ondansetron oral jelly released the drug as rapid manner with improved bioavailability. The observed results were found that the concentration of gelatin carbopol 934 can influenced the release rate & other physico chemical properties. Thus it can be concluded that ondansetron jellies are beneficial in improving the bioavailability of drug as compared to other oral fast releasing dosage forms.

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