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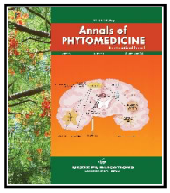

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Regulatory control over chewable gels and current challenges

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Abstract

Chewable gel is a semisolid dosage form. Ease in swallowing, appealing design, and delectable tastes, gummies have become more and more popular in recent years. Young children without their primary teeth can swallow chewable gel. Large population having trouble in swallowing pills, particularly children and the elderly, gummies are the best dosing form, especially for people with dysphagia. The process of heating and congealing is used to create chewable gels. Because of the stability issue, vitamin product formulations provide additional challenges as compared to tablet or capsule. Innovative formulation design may be the key to overcome many of these difficulties. Theoretically, it is possible to include even the most challenging active ingredients into gelatin-based chewables by adjusting pH, using buffer systems, adding excipients that mask tastes, or using encapsulation methods. Often used in pharmaceuticals, nutraceuticals, and over-the-counter medications, it serves as a unique dosage form. The purpose of this review is to summarize the regulatory recommendations prescribed by regulatory authorities such as USA, Japan, Korea, Australia, ICH along with evaluation parameters such as weight variation, pH, water activity, content uniformity, palatability, dissolution test, stickiness, pourability, viscosity, spreadability, microbial Studies, *etc.*

1. Introduction

The most convenient and safest route of administration for active substances is typically thought to be oral administration. Tablets, elixirs, chewables, gummies, soft or hard gel capsules and suspensions are just a few examples of the various oral administration forms available (Gaur and Gananarajan, 2018).

The ease of swallowing, appealing look, and delectable flavours of vitamins provided in chewable gels, often called gummies, have grown in acceptance in recent years, especially for youngsters and senior citizens. By 2025, it is anticipated that the American market for chewable gummies will grow to $4.17 billion (US Pharmacopoeia, 2022; Yan *et al.,*2020).

The term “jelly” refers to a soft, semi-solid preparation that contains both large and small drug particles (Figure 1). Nowadays, jelly candies are particularly popular among kids. It offers an alternative to solid and liquid dose forms (Sabri *et al.,* 2022). It may also be a preferred method of drug administration. Therefore, the need for a more patient-centred delivery approach, particularly *via* the oral route is warranted. The design of a revolutionary medicine delivery system must take into account the paediatric patient’s higher compliance with easier administration, more pleasant and appealing dosage forms (Gurleen and Gananarajan, 2018). Medical jelly may be used to treat systemic and local oral conditions. Oral medicated jellies are palatable solid dose forms that are delivered in the oral cavity and are meant to dissolve in the mouth or pharynx in order to have a local or systemic effect (Ibrahim *et al*., 2017).

Due to the instability of vitamins in a gummy delivery system, the formulation of gummy vitamin products presents additional challenges compared to the manufacturing of tablets or capsules. At temperatures above 110°C, sugars and gelling ingredients are boiled to create gummies. Following boiling, active additives like vitamins and flavourings are added to the mixture at a temperature of 80 to 90°C before it is moulded and dried (Pushpangadan *et al.,* 2014:). Under standard storage temperatures (20-25°C and 50-60% relative humidity), gummy supplements typically have a one- to two-year shelf-life. The main factor affecting the shelf- life of gummies is moisture migration (loss or absorption), which is affected by the manufacturing processes and encasing materials. Gummies may lose or absorb moisture depending on the difference in their water activity and the relative humidity of the environment (US Pharmacopoeia, 2022). An alternative formulation development of dry jelly having a capacity to transform itself in jelly upon addition of water was also suggested. It may help to overcome the problem of thermal stability affected due to heat treatment applied during its formulation. This process may be helpful to formulate heat sensitive drugs. Here, pectin, glucono-α-lactone, sucrose, and dibasic calcium phosphate hydrate was formulated and evaluated. The formulation developed a gelation with water having hardness upto 304 mg/l; without affecting the consistency of jelly. The dissolution behaviour of drugs should be also unaffected in dry jelly formulation (Kakino *et al.,* 2017).

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In individuals with dysphagia, it is discovered that several dose forms, such as pills, capsules, and liquids, are challenging to swallow. Older patients find it difficult to swallow pills or capsules because of their size. (Kadhim, 2019; Imai, 2013; Korean pharmacopoeia, 2014). Patients may experience pain or irritation when a solid preparation comes into touch with their mouth, larynx, or throat, or may sustain a physical harm if the solid preparation rubs against their mucous membranes (Satyanarayana *et al.,* 2011; Yokoyama *et al.,* 2006; Kakino *et al*, 2017).

Drug distribution through the buccal, labial, and sublingual routes is made possible by the use of pharmaceutical jelly as a dosage form. Several medications may also be used in therapies for chronic illnesses. Pharmaceutical jellies are currently sold as over-the-counter medicines in a variety of flavours that include ingredients for anaesthetics, erectile dysfunction, arthritis, antihypertensives, and sore throats. Patients with psychological conditions, thyroid disorders, multiple sclerosis, Parkinson's disease, motion sickness, nausea, and vomiting can use jelly as a treatment option. Medicated jelly is simple to use for patients whose lower jaw is paralysed, uncomfortable, or difficult to chew (Miyazaki, 2020; Rani *et al.,* 2021). Jellies are a safe option for kids who have lost their baby teeth but do not yet have all of their permanent teeth. Drugs from medicated jellies can be released in the mouth and absorbed by oromucosal tissues as well as through the parts of the gastrointestinal tract (Kahrilas, 1994; Sunil *et al.,* 2020).

According to the European Medicines Agency (EMA) and other regulatory bodies, the optimal paediatric formulation should meet the following requirements.

- A Minimum dosage frequency should be required.
- It should have little effect on lifestyle.
- Only excipients that pose little risk should be used.
- It should have convenient, simple, and trustworthy administration.
- It should be simple to make, beautiful, and stable.
- It must be cost effective and marketable.

Figure 1: Chewable gels.

1.1 Advantages of chewable gels

i. It does not require water, easy to handle, making it handy to administer anywhere, at any time (Kramer *et al.,* 2020).

ii. Before ingesting the medicated jelly completely, the drug's therapeutic effect may be stopped by spitting it out (Kahrilas, 1994).

iii. Drugs that are susceptible to liver or gut wall metabolism can also be delivered systemically using this method.

iv. Additionally, the medications that are swallowed after being released from the medicated jelly will enter the digestive tract either in suspended or dissolved form in saliva and will therefore be easily accessible.

v. The delivery of a therapeutic agent to the systemic circulation via the oral mucosa can help overcome issues caused by differences in medication release and retention timeframes (Cizauskaite *et al.,* 2019).

vi. Aspiration risk is decreased, making it the perfect form of drug delivery for people with dysphasia.

vii. Patients who are unable to swallow tablets or capsules, such as the elderly, stroke victims, bedridden patients, patients with esophageal difficulties, and patients who are resistive to swallowing, including paediatric and geriatric patients, can be given pharmaceutical jelly (Breitkreitz *et al.,* 2007; Anonymous, 2006i).

viii. Jellies' good mouthfeel contributes to a shift in medicine's perception.

ix. Pharmaceutical jelly has created new opportunities for business, such as product diversification, product promotion, patent extension, and life cycle management.

x. It Permits heavy drug loading (Raja and Dhoren, 2016).

1.2 Disadvantages of chewable gels

i. The biggest disadvantage is stability. There might be microbial contamination because it mostly consists of water. As a result, preservatives and other excipients must be included.

ii. These dosage forms must be adequately packed to avoid exposure to light and spillage during travel.

iii. Problem of dose measurement is sometimes evident (Sunil *et al.,* 2020; Binns *et al.,* 2018).

1.3 Types of oral jelly

Generally, the jellies may be divided in three categories such as:

1.3.1 Medicated jelly

These jellies have an adequate amount of water and are primarily used on skin and mucous membranes due to their spermicidal, local anaesthetic, and antiseptic properties. Jellies have a local cooling effect once the water has evaporated, and any remaining layer offers protection. For example, ephedrine sulphate jelly is used as a vasoconstrictor to stop nosebleeds (Kaur and Gananarajan, 2018).

1.3.2 Lubricating jelly

These jellies are employed to lubricate various diagnostic instruments, including catheters, surgical gloves, and cystoscopes (Satyanarayana *et al.*, 2011).

1.3.3 Miscellaneous jelly

They are intended for use in a variety of applications, including patch testing and electrocardiography.

1.4 Definition and established name of chewable gels as per different regulatory authorities

1.4.1 Japanese Pharmacopeia

Jellies for oral administration are gelatinous preparations that are non-flowable and have a specific form and size. Jellies for oral application are typically made by combining an active ingredient with adequate excipients and a polymer gel foundation, then, using an appropriate technique, gelatinizing and shaping the mixture into the desired shape and size (Japanese Pharmacopoeia, 2022; Ruheena and Mittapally, 2018).

1.4.2 Therapeutic goods administration

Terms it as gummies or pastille (Anonymous, 2023g).

1.4.3 National cancer institute thesaurus (NCI)

It is classified as 'chewable gel dosage form' (Code C134876) (Anonymous, 2023h).

1.4.4 Clinical data interchange standards consortium (CDISC) defines

It is an elastomeric, formed, or moulded oral gel dosage form that holds its shape and yields to mastication (Anonymous, 2023h).

1.4.5 Korean pharmacopeia

Jellies for oral administration are described as non-flowing gel-like preparations having a particular shape, and may be prepared using various natural gums or other hydrophilic polymers (Kim *et al.,* 2020).

1.4.6 United States Pharmacopoeia, USA (General Chapter <1151>)

Chewable gels are used to administer medication and nutritional supplements orally. Chewable gels may contain all or part of the following ingredients: sugars, water, sweeteners, flavourings, and gelling agent(s). The sweeteners and flavours are meant to improve patient acceptance and cover up the taste of the medicinal component that has been supplied according to the label. Chewable gels are elastic and yield to mastication while maintaining their moulded structure. They should be chewed thoroughly before consuming. In the nutritional supplement and confectionary sectors, chewable gels are also known as "gummies," however the term is not used in official article titles (US Pharmacopoeia, 2022).

1.5 Safety issue

Chewable gels are not preferred to be used as medicinal dosage forms due to the possibility of accidental overdose, despite their appealing candy-like appearance and delectable flavour.

Chewable gel, when consumed like candy, may be hazardous as well. More than 50,000 cases of unfavourable vitamin effects were recorded in 2014 by the American Association of Poison Control Centres. The most common problems associated with adult and paediatric overdoses of fat-soluble vitamins such as vitamin A, D, and K. Even highly informed consumers who are aware of the top tolerated level may suffer overdose problems due to a high (unreported) nutrient overdose (US Pharmacopoeia, 2022).

1.6 Packaging of jellies

Glass jars, plastic bags, and pouches should all be hermetically sealed while storing jelly. It is insufficient to seal a product with paraffin to prevent it from causing problems. Hot jelly will sterilise the container on its own; therefore, containers filled to scalding temperatures (over 83°C) donot need to be pasteurised.

2. Formulation ingredients

2.1 Excipients used formulation of chewable gels

Chewable gels formulation includes following excipients as shown in Table 1.

Table 1: Excipients used in chewable gels

Excipients	Examples	References
Gelling agents	Tragacanth, Sodium alginate, Pectin, Gelatin, Hydroxypropyl methylcellulose K100, Gellan gum, Sugar gum, Xantham gum, Carrageenans, Cellulose derivative.	Suman *et al.,* 2021; Burey *et al.,* 2012; Sharma and Sarwat, 2022
Sweetening agents	Sucrose, Aspartame, Sucralose, Saccharin, Sodium Saccharin, Acesulfame Potassium, Stevia, Sodium cyclamate, Isomalt, Maltose, Neohesperidin dihydrochalcone, Trehalose, Thaumatin, Sorbitol, Maltitol.	Galande *et al.,* 2020; Seremet *et al.,* 2020 Renu *et al.,* 2015
Flavouring agents	Cherry, Lemon, Orange, Grape fruit, Vanilla, Mint, chocolate, Lemon, Grape, Berry, Honey.	Gavaskar *et al.,*2010; Singh and Chellammal. 2022; Gunwantrao *et al.*, 2016
Preservatives	Methyl paraben, Propyl paraben, Benzoic acid, Benzalkonium chloride, Sodium benzoate, Chlorhexidine acetate.	Ishibashi and Endo, 2018
Stabilizers	Propylene glycol, Sorbitol.	Rowe *et al.,* 1999
Solubilizers	Cremophore RH40, PEG 400.	Rowe *et al.,* 1999
pH-adjusting agent	Citric acid, Fumaric acid, Malic acid, Phosphoric acid, Succinic acid, Tartaric acid, Maleic acid, Acetic acid, Hydrochloric acid, Lactic acid, Propionic acid.	Ninomiya *et al.,* 1999
Colouring agents	FD & C Red 40, D & C Reds 3, 22, 28, 33 and 36, FD & C Yellows 5 and 6, D & C Yellow 10, FD & C Blues 1 and 2.	Galande *et al.,* 2020

Acceptable appearance and consistency of jelly is a critical acceptance criteria, which may be achieved using pectin and sodium carboxymethyl cellulose polymers. However, significant increment in the viscosity and hardness of jelly was observed with higher sucrose or pectin concentration (Sabri *et al.*,2022).

2.2 Active pharmaceutical ingredients used in chewable gels formulation

Many active ingredients are reported to be formulated as chewable gels such as:

Loratadine, Diphenhydramine, Desloratadine, Phenylephrine, Chlorpheniramine, Dex-tromethorphan, Doxylamine, Guaifenesin, Fexofenadine, Docusate, Pseudoephedrine, Cetirizine, Triprolidine, Bro Mpheniramine, Ephedrine, Ibuprofen, Acetaminophen (Paracetamol), Ketoprofen, Naproxen, Piroxicam, Meloxicam, leflunomide, Ondansetron, Granisetron, Carbamazepine, Lamotrigine, Clozapine, Olanzapine, Risperidone, Citalopram, Paroxetine, Sertraline, Fluoxetine, Fluvoxamine, Zopiclon, Zolpi-dem, Cimetidine, Ranitidine, Omeprazole, Metoclopramide, Cisapride, Domperidon, Zafirlukast, Montelukast, Pramipexol, Selegiline, Doxazosin, Terazosin, Atenolol, Biso-Prolol, Amlodipine, Nifedipine, Diltiazem, Enalapril, Capto-pril, Ramipril, Losartan, Glyceroltrinitrate, Alfuzosin, Finas-teride, Pravastatin, Atorvastatin, Simvastatin, Gemfibrozil, Metformin, Terfenadine, Celecoxib, Rifecoxib, Rivastignine, Astemizole, Hydroxyzine, Clemastine, Local Anesthestics, Antiseptics, Opioids, opioid, Sildenafil, Tadalafil, Vardenafil, *etc.* (Sirihorachai 2022). Several herbal preparations also have a potential to be prepared as chewable gels (Manoharachary and Nagaraju, 2016; Subramoniam, 2014).

2.3 Method of preparation

The typical formulation may be summarized as follows:

i. **Addition of polymers:** Different concentrations of polymers were used for jellies.

ii. **Addition of gelling agent:** The gelling agent is heated, introduced, and constantly mixed into the sugar syrup.

iii. **Heating:** As the gelling agent completely dissolves, stabilisers and solubilizers are added. After properly mixing the combination, the solution is rapidly heated.

iv. **Stirring:** When the liquid has been completely dissolved, preservatives are added while the mixture is continuously stirred.

v. **Blending of drug:** After adding colour and flavour and stirring continuously, the medicine is added, and the jellies are thoroughly blended.

vi. **Consistency adjustment**: Purified water is used to adjust the final weight and consistency.

vii. **Moulding:** The fluid is then poured into moulds, where it cools to room temperature and solidify as jelly (Salma and Boudouri, 2022; Cebi *et al.,* 2018; Dubey, 2015; Deborah *et al.,* 2015).

3. Challenges in formulating chewable gels

3.1 Stability

USP have suggested to add excessive amounts of nutrients to products in order to make up for losses during storage and extend the length of their shelf-life (US Pharmacopoeia, 2022). Encapsulation of vitamin C in casein gel improved the stability of vitamin C in the gummy at accelerated storage conditions and harsher environments, such as those with higher temperatures and humidity (Yan *et al.,* 2020; Gupta and Sarwat, 2022).

3.2 Palatability

Experts in formulation have a challenging issue since the bitter drugs selected for oral medicated jellies have an unpleasant flavour. Due to the fact that most drugs are unpleasant to swallow, oral disintegrating drug delivery systems sometimes include the drug in a taste-masked form (Sunil *et al.,* 2020). As a result, it is crucial for patient compliance to modify the taste of the formulation.

3.3 Hygroscopicity

Several oral jelly dosage forms are hygroscopic and are unable to maintain their physical integrity at typical temperatures and humidity levels. As a result, they require humidity protection (Sunil *et al.,* 2020).

3.4 Dose/amount of drug

When a medicine has a bitter taste, extra excipients must be added to hide the flavour, which increases the dosage form's ultimate size.

3.5 Aqueous solubility

Different excipients in jelly helps to optimize crystallinity and rigidity of water-soluble medicines, resulting in eutectic combinations.

3.6 Size of jelly

Size affects ease of administration of a jelly, as it affects the process of swallowing. According to observations, jelly with a diameter of 78 mm is the easiest to swallow, while jelly with a diameter of 8 mm or more is the easiest to manage. Consequently, it is challenging to produce jelly that is both easy to handle and easy to swallow (Sunil *et al.,* 2020).

3.7 Drug property

Solubility, crystal morphology, particle size and bulk density of a drug affects the final jelly characteristics.

3.8 Mouth feels

Medicated jellies after oral delivery leave little to no mouth residue. Examples of some marketed jelly products are given in Table 2 (Imai, 2013).

Table 2: Examples of marketed jelly products

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

4. Evaluation of chewable gels

4.1 Water activity

The United States Pharmacopoeia 42-National Formulary 37 (USP42-NF37) utilises the AOAC's Official Methods of Analysis, No. 978.18, which prescribes method to measure the water activity (US Pharmacopoeia, 2022). The gummy was sliced into 2 mm thick circular discs and placed in disposable sample containers. Measurement should be conducted with a benchtop water activity meter at 25°C (Yan *et al.,* 2020; Suman *et al.,* 2021).

4.2 pH analysis

The pH of the gummy was tested with changes in accordance with USP42-NF37 (2019). Sliced gummy bears (1.5 g) and an equal volume of water were put into a centrifuge tube. The sample was vortexed, and the gummy was totally melted after one hour of orbital agitation at 100 rpm in a water bath set at 60°C. The melted gummy was cooled to 27°C, and a pH metre was used to determine its pH. The pH value was set to NMT 4.5 by the Expert Committee (US Pharmacopoeia, 2022; Yan *et al.,* 2020).

4.3 Dissolution test

USP General Chapter <2040> and Japanese Pharmacopeia Chapter <6.10> suggests to evaluate the functional properties of commercial chewable vitamin gels using the phenomenon of dissolution test. It may be useful to ensure that nutrients will be released from the dosage form, using dissolution medium at 37^0C. Any of the three equipments such as apparatus for basket method (apparatus 1), apparatus for paddle method (apparatus 2) or apparatus for flow-through cell method (apparatus 3) may be used.

The dissolution media (900 ml) should be kept at 50 rpm and 37°C (+/- 0.5°C). After 10, 20, 30, 40, 50, 60, 90, and 120 min, 5 ml of the sample should be removed, and the sink condition should be maintained by adding fresh media. A UV spectrophotometer or other suitable technique may be used to evaluate the drug content. After measuring absorbance, the percentage of drug release may also be estimated (US Pharmacopoeia, 2022; Japanese Pharmacopoeia, 2022).

4.4 Weight variation

It is described in the USP General chapter <2091>. It is calculated using the average weight of ten jellies that are individually weighed and blended after being removed from their moulds and placed in a beaker. The chewable gel agrees to the test if the individual weight is not more than a 7.5% deviation from the average weight (US Pharmacopoeia, 2022; Japanese Pharmacopoeia, 2022).

4.5 Color characterization

Using a chromameter calibrated against a typical white tile and set to D65 illuminant/2° observer angle, the colour of the gummy may be measured.

On a white background, a transparent spherical container with a 2 mm-thick sticky slice within was placed. On the sticky surface, reflection was measured. All measurements should be performed in triplicate (Yan *et al.,* 2020).

4.6 Pourability of the mixture

The primary characteristic of jelly is its ease of pourability into moulds due to the use of buffer salts that act as retardants, such as trisodium citrate. These retardants typically raise the pH of the formulation before the addition of acid, which prevents pre-gelation. High retarder concentration leads to the longer setting time and the lower setting temperature, it is also suitable for better setting and pouring texture of the jelly.

4.7 Content uniformity

Content uniformity of the chewable gels may be tested according to Japanese Pharmacopeia (Uniformity of Dosage Units <6.02>). The appropriate analytical method should be used to conduct independent testing on ten units each. Well mixed material should be removed from the individual container and express the results as delivered dose. The requirements for dosage consistency are satisfied if the acceptability value of the first ten dose units is less than or equal to maximum allowed acceptance value (L1) of 15.0, unless otherwise specified. The requirements for dosage uniformity are met if the acceptance value of the first 10 dosage units is less than or equal to L1 %. If the acceptance value is greater than L1 %, test the next 20 dosage units and calculate the acceptance value. The requirements are met, if the final acceptance value of the 30 dosage units is less than or equal to L1% and no individual content of the dosage unit is less than (1– L2 × 0.01) M nor more than (1 – L2 × 0.01) M in calculation of acceptance value under content uniformity or under mass variation. Unless otherwise specified, L1 is 15.0 and L2 is 25.0 (US Pharmacopoeia, 2022; Japanese Pharmacopoeia, 2022).

4.8 Spreadability

Placement of the jelly between two glass slides and uniform flattening with a weight of 1000 gm are the two methods used to determine spreadability. Spreadability helps to test how long it takes the two slides to split (Sunil *et al.,* 2020).

It is calculated by:

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

where,

m = weight tide to upper slide

T = time taken

L = length moved on glass slide

4.9 Stickiness and grittiness

It may be evaluated by rubbing the jelly between two fingers, The stickiness and grit are visually assessed (Sunil *et al.,* 2020).

4.10 Viscosity

A Brookfield viscometer may be used to measure the viscosity. Spindle number four may be employed as the system is non-Newtonian (Sunil *et al.,* 2020; Dosani, 2011).

It is calculated by following formula:

Viscosity in centipoise = Dial reading × Factor

4.11 Syneresis

Syneresis or de-swelling is frequently observed in gels as a result of the loss of liquid, which causes gels to shrink and lower its quality. When a gel is stored, it contracts and the water separates from the gel through a process known as syneresis, specially with a smaller dosage of the gelling ingredient. At room temperature (25°C+/-5°C), all the jellies should be examined for symptoms of syneresis. Syneresis-inducing compositions should be rejected (Narasimharao *et al.,* 2017).

4.12 Microbial studies

These investigations are crucial in establishing the microbiological composition of jellies, as their high-water content makes them more susceptible to microbial development. The ability of the jellies to cultivate diseases including *E. coli, S. aureus, and P. aeruginosa* on a particular medium should be examined.

4.13 Stability studies

An oral gel or jelly that is physically stable should maintain its viscosity, colour, clarity, taste, and odour for the duration of its shelf life. During storage, the presence of syneresis should be examined in gels and jellies. Samples kept at various temperatures provide useful data on the gel's storage needs. The increased temperatures shouldn't be excessively high; most likely, it shouldn't exceed 45 to 50°C. For subjective assessments, a fresh prepared sample should be used as the reference standard (Dosani, 2011; Gohel *et al.,* 2009). List of some marketed product available as chewable gel are shown in Table 3.

Table 3: Marketed medicated chewable gel products

S.No.	Brand name	Active ingredients	References
1.	Nyumi (Ikaria Wellness Private Limited, Mumbai)	Vitamin A (600 mcg), vitamin C (40 mg), vitamin E (10 mg), Vitamin D2(10 mcg), B3(12 mg), B5, B6(2 mg), B9, B12, Amla fruit extract (100 mg), biotin (30 mcg).	Anonymous, 2022a
2.	Zaebees (Johnson & Johnson, United State)	Melatonin (1,2,3 mg)	Anonymous, 2022b
3.	Exhale wellness, Budpop, Hollyweed CBD, Fab CBD, Cheef Botanicals.(Hemp Garden Group, New York)	Cannabidiol (5, 10, 25, 50 mg per gummy)	Anonymous, 2023c
4.	Nutriburst (Nutriburst Ltd, London)	Biotin (40 mcg), calcium, vitamin A (450 mcg) vitamin D (15 mcg, 40 mcg), vitamin C (80 mcg, 60 mg, 30 mg)	Anonymous, 2022d
5.	Bearvana (Biovencer Healthcare Private Limited, Greater Noida)	Amino acid	Anonymous, 2023e

5. Forecast and analysis for the gummy vitamin market by geography and distribution channel for the years 2022-2026

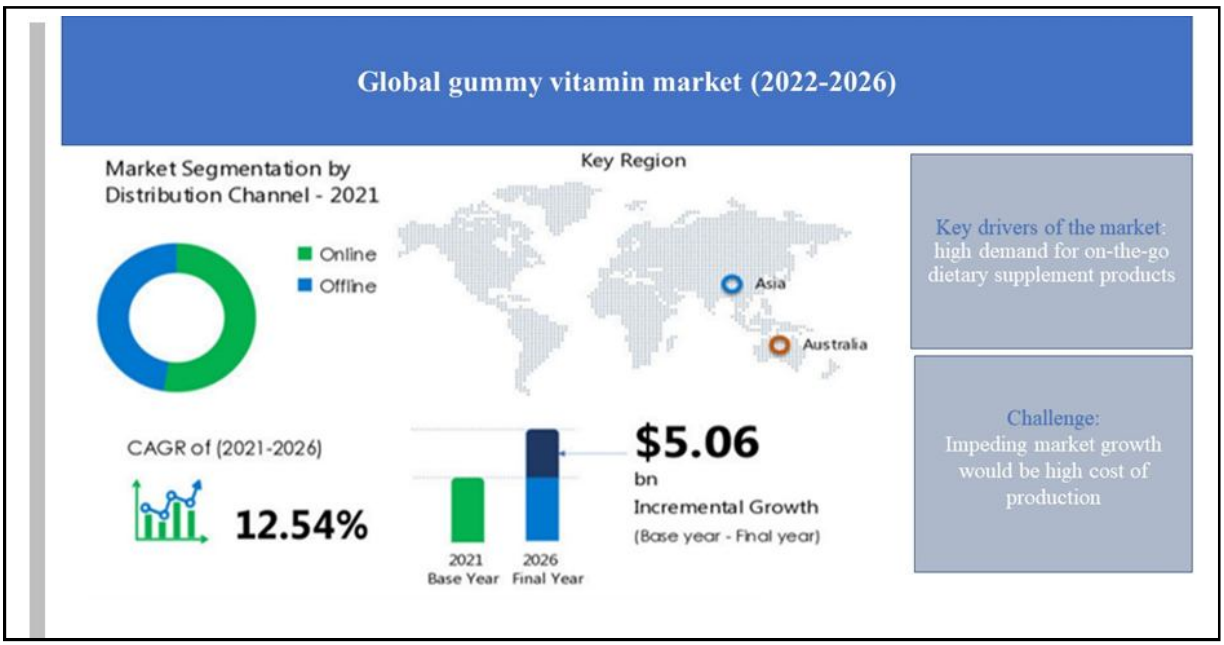

Figure 2: Global gummy vitamin market-forecast and analysis 2022-2026.

One of the key factors driving the growth of the worldwide gummy vitamin market is the rising demand for on-the-go nutritional supplement products to prevent potential illnesses and improve physical and mental well-being (Figure 2). One of the key factors supporting the growth of the global gummy vitamin market is the accessibility of gummy vitamins for children. The high cost of manufacturing resulting from the insufficient supply of vitamin-derived raw materials from nature is one of the major barriers to the growth of the global gummy vitamin industry. In the other regions, Asia-pacific market (APAC) will have the highest growth rate (38%). As a result, during the forecast period, the APAC market for gummy vitamins is anticipated to present significant business possibilities for suppliers. In 2020, the COVID-19 crisis had an effect on the entire gummy vitamin market, as many retailers had to close or modify operations. Walmart announced that it might alter its operating hours, while other businesses intended to temporarily close their locations. The online segment, which had the greatest market share in the base year, presents commercial chances for the gummy vitamin market vendors to seize (Anonymous, 2023f).

6. Conclusion

In comparison to other oral drug delivery systems, chewable gel has a more appealing appearance, taste and increased paediatric patient compliance. Children and patients with dysphagia can use the formulation more successfully and conveniently. By acting quickly and having fast medication absorption and dissolution, it is also able to offer significant therapeutic effectiveness. Since oral jellies have both solid and liquid qualities and are simple to administer without water, they provide an alternative to solid dosage forms. Water activity, pH, weight variation, uniformity of dosage units, and dissolution test (quality control) of chewable gels require careful control to achieve compliance as per current regulatory requirements.

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Conflict of interest

The authors declare no conflicts of interest relevant to this article.

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