Formulation and evaluation of potassium iodide gummies for the prevention of iodine deficiency disorders

Name Of Author:- Divyesh Prashant Gahivad [1st] , Lokesh Devidas Chaudhari [2nd] , Harish Devidas Bodhare [3rd] , Dr. Swapnil Dilip Deo [4th]
Name Of College:- Dr. Uttamrao Mahajan College of B Pharmacy, Chalisgaon

ABSTRACT: -

Iodine deficiency is one of the most prevalent micronutrient deficiency disorders worldwide and is associated with serious health complications such as goiter, hypothyroidism, impaired cognitive development, and cretinism. Although iodized salt and conventional iodine supplements are widely used, factors such as iodine loss during cooking and storage, poor patient compliance, unpleasant taste, and swallowing difficulties limit their effectiveness. Therefore, there is a need to develop an alternative, patient-friendly dosage form that can improve iodine supplementation and therapeutic acceptability.

The present study was aimed at the formulation and evaluation of potassium iodide-loaded pharmaceutical gummies as a novel drug delivery system for iodine supplementation. Three formulations (F1, F2, and F3) were prepared using potassium iodide as the active pharmaceutical ingredient along with gelatin and agar-agar as gelling agents. Additional excipients such as sugar, glucose syrup, citric acid, sodium benzoate, flavouring agent, and colouring agent were incorporated to improve texture, palatability, and stability. The prepared gummies were evaluated for organoleptic properties, weight variation, pH, moisture content, texture analysis, content uniformity, disintegration/chewing time, thickness, and stability studies.

The results demonstrated that all formulations possessed acceptable physicochemical characteristics and patient-friendly properties. Among the prepared formulations, F2 exhibited the most desirable characteristics including optimum texture, lower moisture content, excellent drug content uniformity, better chewability, and improved stability profile. The study concluded that potassium iodide medicated gummies can serve as a promising and effective alternative to conventional dosage forms for iodine supplementation, particularly in pediatric and geriatric populations, by improving patient compliance, palatability, and ease of administration.

KEYWORDS: -

Potassium iodide, Iodine deficiency disorders, pharmaceutical gummies, Novel drug delivery system, Medicated gummies, Goiter, Patient compliance, Iodine supplementation, Gelatin, Thyroid hormones.

INTRODUCTION:-

Iodine is an essential trace element required for the synthesis of thyroid hormones such as thyroxine (T4) and triiodothyronine (T3). These hormones regulate metabolism and are necessary for the proper functioning of vital organs including the liver, kidneys, muscles, brain, and central nervous system. Iodine also plays a key role in controlling energy utilization and is particularly important for the growth and development of the brain and nervous system in infants and young children. The human body contains approximately 15–20 mg of iodine, most of which is stored in the thyroid gland. [1-4].Iodine deficiency is a major global public health problem. Inadequate intake of iodine, especially in pregnant women and women of reproductive age, can lead to severe health complications such as impaired brain development in the fetus, reduced intellectual ability, and other iodine deficiency disorders. These conditions are among the most common causes of preventable intellectual disabilities worldwide. Although iodized salt programs have significantly reduced iodine deficiency since their introduction, recent studies indicate a decline in iodine intake due to changes in dietary habits, reduced consumption of iodized salt, and food processing methods. As a result, a considerable proportion of the global population still suffers from inadequate iodine intake.[2-5].

To overcome this issue, alternative and patient-friendly dosage forms are required to ensure adequate iodine supplementation. Conventional dosage forms such as tablets and capsules may not be suitable for children and elderly individuals due to swallowing difficulties and poor compliance.[6]Gummies are chewable, palatable dosage forms that have gained popularity in the pharmaceutical and nutraceutical industries due to their ease of administration, attractive appearance, and improved patient compliance. They are especially suitable for pediatric and geriatric populations.[7,8] In this study, iodine gummies were formulated using potassium iodide as the source of iodine. Potassium iodide is a water-soluble and commonly used pharmaceutical compound that provides a reliable and effective source of iodine for supplementation. The incorporation of potassium iodide into gummy formulations ensures uniform distribution of iodine and accurate dosing. [8,9]

Thus, the present work focuses on the formulation and evaluation of iodine gummies containing potassium iodide as an alternative dosage form to improve iodine supplementation and help in the prevention of iodine deficiency disorders.[3,4,7]

1. What is iodine deficiency?

Iodine deficiency remains one of the most significant and preventable nutritional disorders worldwide, affecting millions of individuals across both developing and developed nations. Iodine is an essential micronutrient required in trace amounts for normal physiological functioning, particularly for the synthesis of thyroid hormones. Despite global efforts such as universal salt iodization programs, iodine deficiency continues to persist due to various socioeconomic, environmental, and dietary factors.[2,3,4]

Iodine deficiency disorders (IDD) encompass a spectrum of clinical conditions resulting from insufficient iodine intake. The most visible manifestation is Goiter, characterized by enlargement of the thyroid gland due to compensatory mechanisms. In severe cases, particularly during pregnancy and early childhood, iodine deficiency can lead to irreversible conditions such as Cretinism, associated with profound mental retardation and stunted growth. Additionally, inadequate iodine levels can result in Hypothyroidism, marked by reduced thyroid hormone production and metabolic disturbances.[3,4,19,20]

The global burden of iodine deficiency is particularly concerning in regions where soil iodine content is low, leading to reduced iodine levels in food crops. Populations with limited access to iodized salt or those consuming iodine-poor diets are at higher risk, especially pregnant women and children.[2,3,4]

Signs and symptoms of iodine deficiency:-[4,19,20]

- Slow heart rate
- Hair loss
- Unexpected weight gain
- Brain fogg
- Muscle soreness
- Memory loss
- Swelling in the neck
- Brittle nails
- Dry skin
- Depression and headache
- Feeling colder than usual

Table 1:- Recommendations for iodine intake (mg/day) by age or population group:-

Age	Acc. To U.S. Institute of Medicine	Age	Acc. To World Health Organization
Infants 0–12 months	110-130 mg	Children 0-5 years	90 mg
Children 1-8 years	90 mg	Children6-12 years	120 mg
Children 9-13 years	120 mg		
Adults n 9-13 years	150 mg	Pregnancy Adults >12 years	150 mg
Pregnancy	220 mg	Pregnancy	250 mg
Lactation	290 mg	Lactation	250 mg

2. SPECIFIC IODINE DEFICIENCY DISORDERS

1. GOITER:-[13,14]

Goiter is an abnormal enlargement of the thyroid gland, which is a butterfly-shaped gland located at the base of the neck, just below the Adam's apple. The thyroid is responsible for producing hormones that regulate metabolism, energy levels, and growth. A goiter can vary in size from small, non-visible lumps to large, noticeable swelling that can cause discomfort or difficulty swallowing and breathing.

Goiter has been recognized for thousands of years, with its earliest documented descriptions dating back to ancient civilizations. In modern medicine, goiter is typically associated with thyroid dysfunction, either overproduction (hyperthyroidism) or underproduction (hypothyroidism) of thyroid hormones. However, goiter can also occur in cases where thyroid hormone levels remain normal, often due to iodine deficiency or autoimmune conditions. Despite its association with thyroid disease, goiter can have several causes and may present with a variety of symptoms ranging from cosmetic concerns to severe health complications.

The prevalence of goiter varies worldwide, with higher rates seen in regions with iodine deficiency, as iodine is an essential component for thyroid hormone production. The disease can affect individuals of all ages but is more commonly seen in adults, particularly women. Although the condition is often treatable, it may require lifelong management in some cases, especially when linked to chronic thyroid disorders.

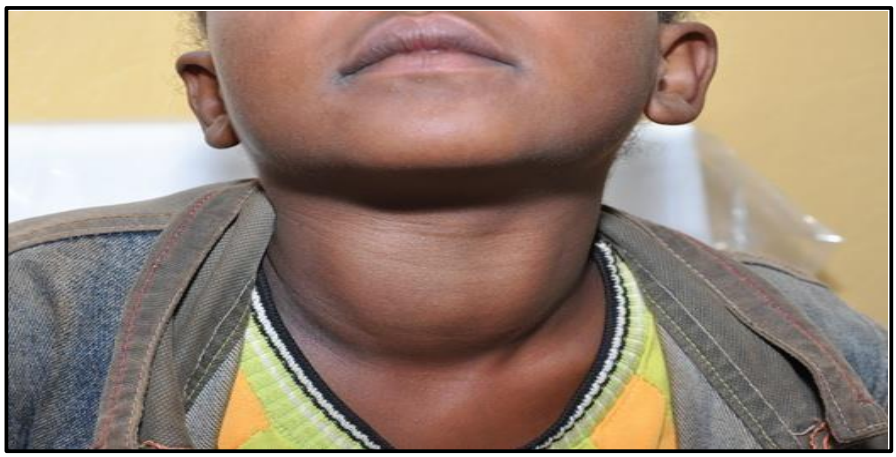
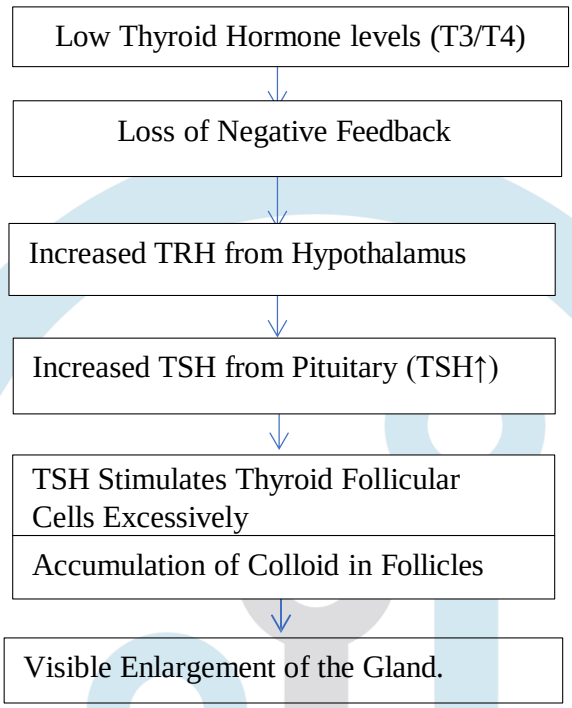


Fig No. 01: Goiter



MECHANISM OF

GOITER FORMATION:-

Goiter develops primarily due to a deficiency of thyroid hormones, usually caused by inadequate iodine intake. When the thyroid gland cannot synthesize sufficient T3 and T4, the normal negative feedback to the hypothalamus and pituitary gland is lost. As a result, the hypothalamus releases increased amounts of Thyrotropin-Releasing Hormone (TRH), which in turn stimulates the anterior pituitary to secrete higher levels of Thyroid-Stimulating Hormone (TSH). Excess TSH continuously stimulates the thyroid follicular cells, causing them to grow, proliferate, and produce more thyroglobulin. However, due to the lack of iodine, this thyroglobulin cannot be effectively converted into active thyroid hormones, leading to the accumulation of colloid within the follicles. Gradually, this excessive stimulation and colloid accumulation cause enlargement of the thyroid gland, resulting in a visible swelling in the neck known as goiter.

Symptoms of Goiter:-

- Visible swelling in the neck
- Difficulty swallowing
- Difficulty breathing
- Hoarseness or voice changes.
- Neck discomfort.

Epidemiology:-

Endemic goiter is when a large number of people in a group have an enlarged thyroid gland, and it is usually caused by not getting enough iodine in their daily diet. This condition is considered endemic when more than 5% of children aged 6 to 12 years have swollen thyroid glands. Many mountainous areas around the world, both past and present, have been or still are regions where endemic goiter is common. This disease can be found in the Andes Mountains, across the Himalayas, in parts of the European Alps where iodine supplements haven't reached everyone, in Greece and Middle Eastern countries, in various areas of China, and in the highlands of New Guinea. There were also significant endemic areas in non-mountainous regions, like the grasslands of Cameroon and parts of northern Zaire and the Central African Republic up to the borders of Uganda and Rwanda, as well as in Holland, Central Europe, and the interior of Brazil. In North America, the Great Lakes region had an endemic goiter problem until it was controlled through the use of iodized salt in the early 1900s.Various countries have created goiter maps that show where the disease is present, and these maps have changed over time as prevention efforts have improved. While goiter was a major issue in many parts of the United States in the past, recent surveys show that it now affects no more than 4 to 11% of schoolchildren, which shows that iodine levels have remained sufficient since 1988. This is a sign that iodine prevention programs have been effective in reducing endemic goiter. The global and regional spread of goiter was thoroughly examined by Kelly and Snedden in 1960, and more recently, in 2005.

2. CRETINISM:-[15,16,17]

Cretinism is a severe congenital condition resulting from profound thyroid hormone deficiency during fetal or early neonatal life, most commonly due to maternal iodine deficiency. Thyroid hormones play a vital role in the regulation of growth, brain maturation, metabolic activities, and neurodevelopment during pregnancy. When the developing fetus is deprived of adequate thyroid hormones, especially during the critical period of early gestation, irreversible damage occurs to the central nervous system, leading to mental retardation, impaired motor function, deaf-mutism, stunted physical growth, and characteristic facial features. Cretinism is therefore considered one of the most serious outcomes of iodine deficiency disorders and remains a major public health concern in regions where dietary iodine intake is insufficient. The condition is largely preventable through adequate iodine nutrition, making early intervention and universal salt iodization key strategies for its global control.

TYPES OF CRETINISM:-

1. Neurological Cretinism :- Mainly affects brain development,mental retardation is prominent

2. Myxedematous cretinism:-Mainly affects thyroid gland and physical growth.Severe growth

retardation.

PATHOPHYSIOLOGY:-

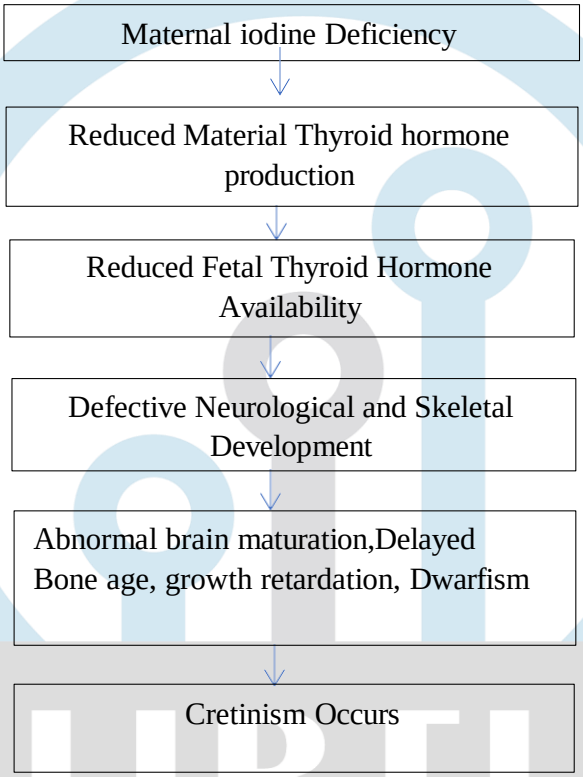


Fig No.02: Cretinism

Cretinism develops as a result of severe iodine deficiency, which leads to decreased synthesis of the thyroid hormones triiodothyronine (T3) and thyroxine (T4) in the mother during pregnancy. Iodine is an essential component required for the formation of these hormones.

When maternal iodine intake is insufficient, the maternal thyroid gland is unable to produce adequate amounts of T4. Since the developing fetus is completely dependent on maternal thyroid hormones during the early stages of life, especially during the first trimester, a deficiency of maternal T4 results in fetal hypothyroidism.

Thyroid hormones play a crucial role in neuronal development, including neuronal migration, myelination, synaptogenesis, and the maturation of the central nervous system. When fetal T4 levels fall, these neurological processes are severely impaired. As a consequence, the fetus experiences defective development of the cerebral cortex, cochlea, and motor pathways, ultimately leading to irreversible mental retardation, deaf-mutism, motor spasticity, and impaired coordination. This neurological damage is permanent because the brain is highly sensitive to thyroid hormone deficits during critical developmental periods.

Additionally, thyroid hormones regulate normal skeletal growth and bone maturation. In the absence of adequate levels, the fetus and newborn exhibit delayed bone age, growth retardation, and characteristic dwarfism. Low thyroid hormone levels stimulate increased secretion of thyroid-stimulating hormone (TSH) from the fetal pituitary through a negative feedback mechanism. Persistently elevated TSH causes hypertrophy and hyperplasia of the fetal thyroid gland, which may result in goiter formation.

Thus, the overall pathophysiology of cretinism involves a sequence beginning with maternal iodine deficiency, followed by impaired thyroid hormone production, reduced fetal thyroid hormone availability, defective neurological and skeletal development, and compensatory enlargement of the thyroid gland. The resulting abnormalities in brain maturation, hearing development, and physical growth produce the classical clinical manifestations of cretinism.

Major Symptoms :-

- Severe mental retardation
- Poor learning ability
- Problems in walking
- Dwarfism
- Large tongue
- Dry skin
- Slow heart rate.

Current Strategies to Combat Iodine Deficiency

Universal salt iodization (USI) is the most widely adopted strategy to control iodine deficiency worldwide. This approach involves fortification of common salt with iodine and has significantly reduced IDD prevalence. [2,5]

Other methods include iodine supplementation through tablets, capsules, and fortified foods. Public health initiatives and awareness programs have contributed to improved iodine intake globally. [2-5,11]

However, these strategies have limitations. Iodine loss during cooking and storage reduces its effectiveness. Additionally, inconsistent consumption patterns and dietary habits contribute to uneven iodine intake. [2,3,6]

Limitations of Conventional Dosage Forms:- [6-8,20]

Conventional dosage forms such as tablets, capsules, and liquid formulations are widely used for drug delivery. However, they present several limitations that can affect therapeutic effectiveness, patient compliance, and overall treatment outcomes.

- Poor Patient Compliance
- Swallowing Difficulties (Dysphagia).
- Unpleasant Taste and Odor
- Delayed Onset of Action
- Variable Bioavailability
- Stability Issues (Especially Liquids)
- Dose Inaccuracy (Liquids)
- Storage and Handling Issues

Aim and Objective: -

Iodine deficiency continues to be a major public health concern worldwide despite the implementation of preventive strategies such as universal salt iodization. Inadequate iodine intake remains prevalent in many populations due to dietary habits, improper storage of iodized salt, and loss of iodine during cooking. These factors contribute to the persistence of iodine deficiency disorders, including Goiter, Cretinism, and Hypothyroidism, which significantly affect growth, cognitive development, and metabolic functions.[2-5,11,15]

Conventional iodine supplementation methods, such as tablets, capsules, and syrups, are associated with several limitations, including poor patient compliance, difficulty in swallowing, unpleasant taste, and dosing inaccuracies. These issues are particularly evident in pediatric and geriatric populations, who are most vulnerable to iodine deficiency and require user-friendly dosage forms for effective supplementation.[6,8,20]

Furthermore, iodized salt, although widely used, does not always ensure consistent iodine intake due to variability in consumption patterns and iodine degradation during storage and cooking processes. This highlights the need for alternative delivery systems that can provide a controlled and accurate dose of iodine.[2,5,18]

Pharmaceutical gummies have emerged as a promising novel drug delivery system that combines therapeutic efficacy with patient acceptability. Their chewable nature, pleasant taste, and ease of administration make them highly suitable for improving adherence to supplementation regimens. Additionally, gummies allow for effective taste masking and uniform distribution of active ingredients, ensuring consistent dosing.[7,8,20,21]

Despite these advantages, limited research has been conducted on the formulation and evaluation of iodine-loaded gummies. There is a lack of comprehensive studies addressing their physicochemical properties, stability, and performance as an iodine delivery system. Therefore, the development of pharmaceutical gummies for iodine supplementation represents a significant area of research with potential benefits in improving public health outcomes.[7,8,22]

Scope of the study

The present study focuses on the formulation and evaluation of pharmaceutical gummies as a novel drug delivery system for iodine supplementation. Iodine deficiency remains a significant public health concern despite the widespread use of iodized salt, primarily due to inconsistent intake and loss of iodine during storage and cooking. This necessitates the development of alternative dosage forms that can provide accurate dosing and improved patient compliance.[2-5,11,15]

The study aims to develop a palatable and stable gummy formulation containing iodine, suitable for populations with swallowing difficulties such as children and elderly patients. By improving taste and ease of administration, gummies may enhance adherence compared to conventional dosage forms like tablets and syrups. The research includes evaluation of key parameters such as physicochemical properties, content uniformity, and stability to ensure quality and effectiveness of the formulation.[6-8,20,22]

Furthermore, this study explores the potential application of iodine gummies in nutritional supplementation programs to prevent iodine deficiency disorders such as Goiter and Hypothyroidism. The findings of this work may provide a basis for future research, including bioavailability and clinical studies, as well as the development of patient-friendly iodine delivery systems.[3-7,21,22]

LITERATURE SURVEY: -

1. Michael B. Zimmermann et al. (2009)-

This review explained the global prevalence of iodine deficiency disorders and highlighted the importance of iodine in thyroid hormone synthesis and neurological development. The study emphasized that iodine deficiency remains one of the leading causes of preventable mental retardation worldwide and discussed the effectiveness of iodine supplementation and universal salt iodization programs in reducing IDDs.

2. Michael B. Zimmermann and Kris Boelaert (2015)-

This article discussed the relationship between iodine deficiency and thyroid disorders such as goiter, hypothyroidism, and impaired cognitive development. The review also highlighted the persistence of iodine deficiency in several countries despite public health interventions and emphasized the need for alternative iodine supplementation approaches.

3. World Health Organization, UNICEF, and ICCIDD (2007)-

The report provided guidelines for the assessment, prevention, and monitoring of iodine deficiency disorders. It emphasized the significance of adequate iodine intake during pregnancy and childhood and recommended universal salt iodization as the primary preventive strategy against IDDs.

4. Andersson M. et al. (2010)-

This review focused on the epidemiology of iodine deficiency and the role of salt iodization in maintaining adequate iodine nutrition. The study highlighted that several populations still suffer from insufficient iodine intake because of poor dietary practices and inadequate iodine fortification programs.

5. Arya V. et al. (2010)-

This study discussed the limitations of conventional dosage forms such as tablets, capsules, and syrups in pediatric and geriatric patients. The authors reported that swallowing difficulties, poor palatability, and reduced compliance necessitate the development of patient-friendly drug delivery systems.

6. Patel A. et al. (2021)-

This review described pharmaceutical gummies as a novel oral drug delivery platform with improved patient compliance and acceptability. The study highlighted the advantages of gummies, including ease of administration, chewability, taste masking, and suitability for pediatric and geriatric populations.

7. Hetzel B.S. et al. (1983)-

This article explained the role of iodine supplementation in preventing endemic goiter and other iodine deficiency disorders. The study concluded that adequate iodine intake is essential for maintaining thyroid health and normal metabolic activity.

8. United States Pharmacopeia (Latest edition)-

The monograph described the pharmaceutical properties, standards, and therapeutic applications of potassium iodide. It highlighted potassium iodide as an effective and commonly used source of iodine for the prevention and treatment of iodine deficiency disorders.

9. Aulton M.E. et al. (2018)-

This pharmaceutical review explained the formulation and manufacturing principles of novel drug delivery systems including medicated gummies. The study discussed the role of gelling agents, sweeteners, flavoring agents, and preservatives in maintaining gummy texture, stability, and patient

acceptability.

10. Rowe R.C. et al. (2017)-

This handbook provided detailed information regarding pharmaceutical excipients such as gelatin, agar, citric acid, glucose syrup, and sodium benzoate used in gummy formulations. The review highlighted their functional roles in improving texture, stability, and shelf-life.

11. Allen L.V. et al. (2014)-

This study discussed pharmaceutical dosage forms and emphasized the growing importance of chewable and palatable formulations in improving patient compliance. The review also highlighted the advantages of medicated gummies in oral drug delivery systems.

12. Rajeev Garg, Aditi D. Raval, Mohit Kumar, et al (2025)-

This review evaluated the development and characterization of medicated gummies and reported that gummy dosage forms exhibit improved patient compliance, effective taste masking, and acceptable physicochemical properties compared with conventional formulations.

13. Kawther Khalid Ahmed, Hanan Jalal Kassab, Intesar Jawad Al Ramahi, Zahraa Salim Alwan, et al (2023)-

This article reviewed the formulation and evaluation of chewable medicated gummies prepared using gelatin and agar-based systems. The study concluded that gummies can successfully deliver active pharmaceutical ingredients with improved palatability and stability.

14. Remington: The Science and Practice of Pharmacy (2020)-

This pharmaceutical reference described the formulation principles of oral medicated gummies and explained the importance of moisture control, texture optimization, and stability studies in developing effective gummy dosage forms.

15. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry (2011)-

This textbook provided information regarding the medicinal and pharmaceutical importance of iodine compounds, especially potassium iodide, in thyroid hormone synthesis and management of iodine deficiency disorders.

Plan of Work:-

1. Literature survey and collection of relevant research articles
2. Study of iodine deficiency
3. Selection of suitable active ingredient and excipients
4. Procurement of materials and chemicals
5. Pre-formulation studies of selected ingredients
6. Compatibility study of iodine with excipients
7. Preparation of pharmaceutical gummies by heating and molding method
8. Evaluation of prepared gummies for:
    - Macroscopical Evaluation
    - Weight variation
    - pH
    - Moisture Content
    - Texture Analysis
    - Content uniformity
    - Disintegration Appearance time
9. Stability studies of optimized formulation
10. Interpretation of results and discussion
11. Conclusion of the study

PHARMACEUTICAL GUMMIES AS A NOVEL DRUG DELIVERY:-

[7,8,20,22]

Pharmaceutical gummies have emerged as a promising novel drug delivery system (NDDS) that combines therapeutic effectiveness with patient-friendly characteristics. Gummies are chewable dosage forms prepared using gelling agents such as gelatin or pectin, along with sweeteners, flavoring agents, and active pharmaceutical ingredients. Their soft texture, attractive appearance, and pleasant taste make them highly acceptable among patients, especially children. Unlike conventional dosage forms, gummies do not require water for administration and are easy to consume, making them convenient for daily use.

The incorporation of iodine into a gummy formulation represents a novel and effective approach for the management of iodine deficiency. By delivering iodine in a palatable and chewable form, pharmaceutical gummies can significantly enhance patient compliance and ensure consistent intake of the micronutrient. Additionally, gummies offer flexibility in formulation, allowing for the incorporation of precise doses of iodine along with suitable excipients to maintain stability and quality.

However, the development of iodine-containing gummies requires careful consideration of formulation parameters, including the stability of iodine, uniform distribution within the matrix, and maintenance of appropriate texture and shelf-life. Despite these challenges, pharmaceutical gummies present a highly promising NDDS for improving the management of iodine deficiency and addressing the limitations of conventional dosage forms.

Rational for using gummies for iodine delivery

Rational use of medicines means that patients receive medications appropriate to their clinical needs, in the correct dose, for an adequate duration, and at the lowest cost. Applying this concept to iodine supplementation ensures effective prevention of iodine deficiency while minimizing risks of under- or over-dosage.[2,11,20]

Pharmaceutical gummies offer a rational and innovative solution to these challenges by functioning as a patient-friendly novel drug delivery system (NDDS). The primary rationale for using gummies in iodine deficiency lies in their ability to significantly improve patient compliance. Their chewable nature, pleasant taste, and attractive appearance encourage regular consumption, which is essential for maintaining adequate iodine levels in the body. Unlike traditional dosage forms, gummies do not require water and are easy to administer, making them convenient for daily use.[6-8,22]

Another important rationale is the effective taste masking capability of gummy formulations. Iodine compounds may have an unpleasant taste or odor, which can reduce patient willingness to consume supplements regularly. The use of sweeteners and flavoring agents in gummies helps in masking these undesirable characteristics, thereby enhancing acceptability.[7,8,20]

Gummies also allow for accurate and uniform dose delivery, ensuring that each unit contains a precise amount of iodine. This is particularly important in micronutrient supplementation, where both deficiency and excess can lead to adverse effects. Furthermore, gummies provide formulation flexibility, enabling the incorporation of additional nutrients if required, and allowing the development of sugar-free or plant-based formulations using pectin instead of gelatin.[7-9,16]

From a public health perspective, gummies can serve as an effective alternative or complementary strategy to iodized salt programs, especially in populations where salt intake is restricted or inconsistent. They are also suitable for targeted supplementation in high-risk groups such as children, adolescents, and pregnant women. However, the rational use of gummies also requires consideration of formulation challenges such as iodine stability, moisture sensitivity, and microbial contamination.

Proper selection of excipients and optimized manufacturing processes are essential to ensure product quality and shelf-life.[2,7,15-17]

ADVANTAGES OF IODINE GUMMIES:-[2-5,20-22,25]

1. Improved Patient Compliance

Chewable, palatable dosage form → better acceptance

Particularly beneficial for:

- Children
- Elderly
- Patients with swallowing difficulty
- Overcomes compliance issues seen with tablets/capsules

2. Taste Masking of Iodine

Iodine often has an unpleasant taste and odor Gummy

effectively masks taste

Enhances regular consumption

3. Accurate and Uniform Dosing

Each gummy contains a precise quantity of iodine

Ensures consistent intake compared to household iodized salt Helps to

prevent underdosing or overdosing

4. Ease of Administration

No water required

Can be consumed anywhere

Suitable for mass supplementation programs

5. Targeted Use in High-Risk Populations

Useful in:

- Pregnant women
- Children (growth & brain development stage)

Helps prevent disorders like:

- Goiter
- Cretinism
- Hypothyroidism

6. Combination Potential

Gummies can be multi-nutrient carriers:

- Iodine + Iron
- Iodine + Vitamins (A, D, B-complex)

Useful in addressing multiple deficiencies simultaneously

DRUG AND EXCIPIENT PROFILE:-[8,20,26-32]

1. Potassium Iodide

Fig .03: Potassium Iodide

Common Name: Potassium iodide

Chemical Name: Potassium iodide

IUPAC Name: Potassium iodide

Source: Inorganic iodide salt prepared commercially

Chemical Formula: KI

Chemical Structure:

Molecular Weight: 166.00 g/mol

Appearance: White crystalline powder, odorless, highly water soluble

Pharmacological Action: Iodine supplementation; supports thyroid hormone synthesis

Therapeutic Uses: Prevention and treatment of iodine deficiency disorders and goiter

Adverse Effects: Excess intake may cause iodism, nausea, metallic taste, thyroid dysfunction

Contraindications: Hyperthyroidism, iodine hypersensitivity

2. Gelatin

Fig .04: Gelatin

Common Name: Gelatin

Chemical Name: Hydrolyzed collagen protein

IUPAC Name: Not specifically defined (natural protein derivative)

Source: Obtained from collagen of animal connective tissues and bones

Chemical Formula: Protein complex (no fixed formula)

Chemical Structure :

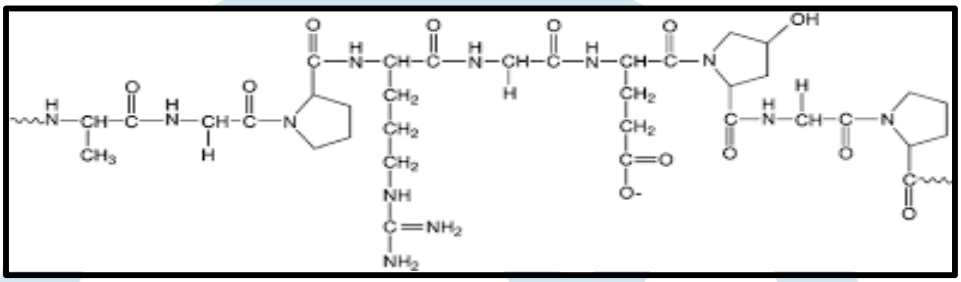


Fig.05: Structure Of Gelatin

Molecular Weight: Variable

Appearance: Light yellow to colorless powder or granules

Pharmacological Action: Gelling and thickening agent **Therapeutic**

Uses: Used in capsules, gummies, and food products **Adverse Effects:**

Rare allergic reactions

Contraindications: Avoid in patients with gelatin hypersensitivity

3. Agar-Agar

Common Name: Agar-agar

Chemical Name: Agar

IUPAC Name: Polysaccharide complex from red algae

Source: Obtained from red seaweed species

Chemical Formula: Complex polysaccharide

Fig .06: Agar-Agar

Chemical Structure:

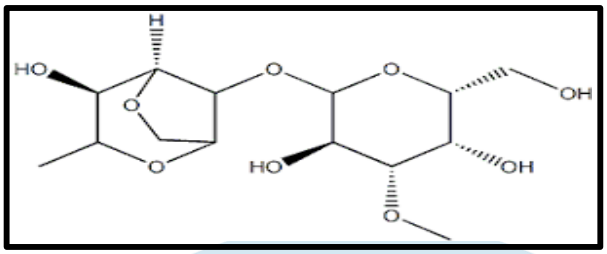


Fig. 07: Structure Of Agar-Agar

Molecular Weight: Variable

Appearance: Off-white powder or flakes

Pharmacological Action: Gelling and stabilizing agent **Therapeutic**

Uses: Used in pharmaceutical and food formulations **Adverse Effects:**

Excess consumption may cause bloating

Contraindications: Use cautiously in gastrointestinal obstruction

4. Sugar

Fig.08: Sugar

Common Name: Sugar

Chemical Name: Sucrose

IUPAC Name: α-D-glucopyranosyl-(1→2)-β-D-fructo-furanoside

Source: Obtained from sugarcane or sugar beet

Chemical Formula: $C_{12}H_{22}O_{11}$

Chemical Structure:

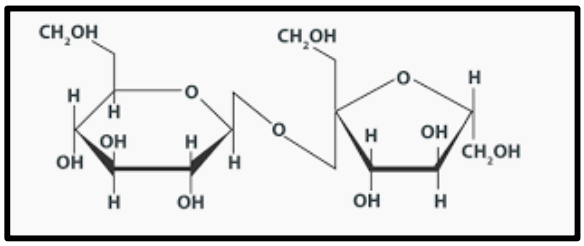


Fig.09: Structure Of Sucrose

Molecular Weight: 342.30 g/mol

Appearance: White crystalline powder

Pharmacological Action: Sweetening agent

Therapeutic Uses: Improves palatability and texture

Adverse Effects: Excess intake may contribute to dental caries and obesity

Contraindications: Diabetes mellitus (excess use)

5. Glucose Syrup

Fig.10: Glucose Syrup

Common Name: Glucose syrup

Chemical Name: Hydrolyzed starch syrup

IUPAC Name: Mixture of glucose oligosaccharides

Source: Prepared from hydrolysis of starch

Chemical Formula: Variable

Chemical Structure

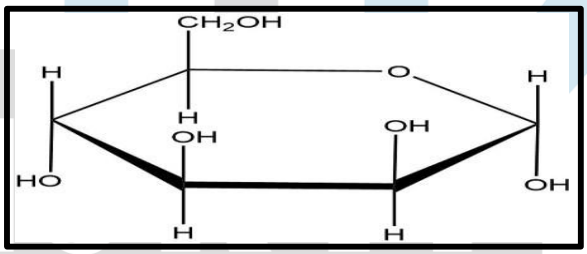


Fig.11: Structure Of Glucose

Molecular Weight: Variable **Appearance:**

Clear viscous syrup

Pharmacological Action: Sweetening and plasticizing agent

Therapeutic Uses: Prevents crystallization and improves gummy texture

Adverse Effects: Excess intake may increase blood sugar levels

Contraindications: Diabetes mellitus

6. Citric Acid

Fig.12: Citric Acid

Common Name: Citric acid

Chemical Name: Citric acid

IUPAC Name: 2-Hydroxypropane-1,2,3-tricarboxylic acid

Source: Citrus fruits or microbial fermentation

Chemical Formula: $C_6H_8O_7$

Chemical Structure:

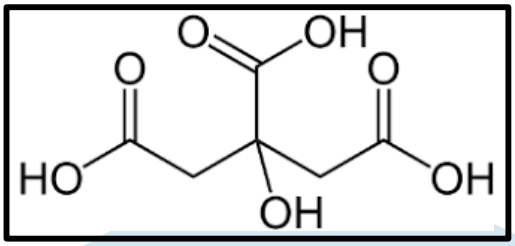


Fig.13: Structure Of Citric Acid

Molecular Weight: 192.12 g/mol

Appearance: White crystalline powder

Pharmacological Action: Acidulant and pH adjusting agent

Therapeutic Uses: Improves flavor and maintains pH

Adverse Effects: Excess use may cause gastric irritation

Contraindications: Hypersensitivity to citric acid

7. Sodium Benzoate

Fig.14: Sodium Benzoate

Common Name: Sodium benzoate

Chemical Name: Sodium benzoate

IUPAC Name: Sodium benzenecarboxylate

Source: Synthetic preservative

Chemical Formula: $C_7H_5NaO_2$

Chemical Structure:

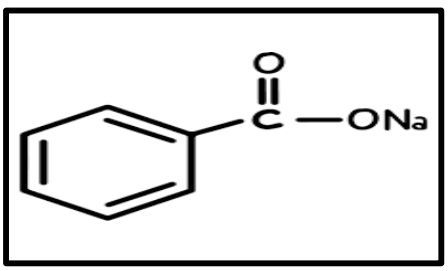


Fig.15: Structure Of Sodium Benzoate

Molecular Weight: 144.11 g/mol

Appearance: White crystalline powder

Pharmacological Action: Antimicrobial preservative

Therapeutic Uses: Prevents microbial contamination in formulations

Adverse Effects: Rare allergic reactions or irritation

Contraindications: Hypersensitivity to benzoates

8. Peppermint Oil

Fig.16: Peppermint Oil

Common Name: Peppermint oil

Chemical Name: Mentha piperita oil

IUPAC Name: N/a (Mixture of menthol and volatile compounds)

Source: Extracted from peppermint leaves

Chemical Formula: Variable mixture

Chemical Structure : N/A

Molecular Weight: Variable

Appearance: Clear, colorless to pale yellow liquid with mint odour

Pharmacological Action: Flavoring and cooling agent

Therapeutic Uses: Masks unpleasant taste and odor

Adverse Effects: May cause irritation in sensitive individuals

Contraindications: Hypersensitivity to peppermint oil

Table 2- FORMULATION OF IODINE GUMMIES :-

Sr. No	Ingredients	F1	F2	F3	ROLE
1	**Potassium iodide**	100 mg	100 mg	100 mg	Active pharmaceutical ingredient (thyroid supplement, iodine source)
2	**Gelatin**	6 g	8 g	5 g	Gelling agent – provides elasticity and chewiness
3	**Agar-agar**	4 g	6 g	3 g	Secondary gelling agent – improves firmness and reduces stickiness
4	**Sugar**	20 g	20 g	20 g	Sweetening agent and provides structure/body
5	**Glucose syrup**	15 g	15 g	15 g	Prevents crystallization, enhances smooth texture and chewiness
6	**Citric acid**	0.3 g	0.3 g	0.3 g	Acidulant – improves taste and maintains pH
7	**Sodium benzoate**	0.2 g	0.2 g	0.2 g	Preservative – prevents microbial growth
8	**Peppermint oil**	q.s.	q.s.	q.s.	Flavoring agent – masks unpleasant taste&odourof drug
9	**Purified water**	up to 100 ml	up to 100 ml	up to 100 ml	Vehicle / solvent for preparation

METHODOLOGY:-[33-38]

Preparation of Potassium Iodide Gummies

- **Ingredients**

Potassium iodide, gelatin, agar-agar, sucrose, glucose syrup, citric acid, sodium benzoate, orange flavour, sunset yellow, and purified water were used for the preparation of gummies.

➢ Method of Preparation

Step 1: Preparation of Gelatin Base

Accurately weighed gelatin was dispersed in a measured quantity of purified water and allowed to stand for **10–15 minutes at room temperature** to facilitate blooming. This step ensured proper hydration and uniform dissolution of gelatin.

Step 2: Preparation of Agar Solution

Agar-agar was dissolved separately in purified water by heating with continuous stirring until a clear solution was obtained. Complete dissolution was ensured to avoid lump formation.

Step 3: Preparation of Sugar Syrup

Sucrose and glucose syrup were mixed with a small quantity of purified water and heated with continuous stirring. The mixture was heated to **105–110°C (soft ball stage)** to obtain a concentrated syrup, which is essential for proper texture and prevention of stickiness.

Step 4: Mixing of Base Components

The prepared agar solution was added to the hot sugar syrup with continuous stirring. Subsequently, the bloomed gelatin was incorporated into the mixture and stirred until a homogeneous viscous mass was obtained.

Step 5: Cooling of Mixture

The mixture was allowed to cool to **40–50°C** to prevent degradation of the active ingredient and volatile components.

Step 6: Incorporation of Drug and Excipients

Potassium iodide was added to the cooled mixture with continuous stirring to ensure uniform distribution. Citric acid and sodium benzoate were then incorporated, followed by addition of flavouring agent and colouring agent (q.s.).

Step 7: Moulding

The final mixture was poured into pre-lubricated moulds carefully to avoid air entrapment.

Step 8: Setting and Drying

The filled moulds were allowed to stand at room temperature or under refrigeration until complete setting occurred. The prepared gummies were then subjected to **drying for 12–24**

hours to reduce surface moisture and stickiness.

Step 9: De-moulding and Storage

After complete setting and drying, gummies were removed from moulds and stored in airtight containers to protect them from moisture and microbial contamination.

Fig.17: Ingredients

Fig.18: Weighed Ingredients

Fig.19: Preparations

Fig.20: Preparations Is transferred

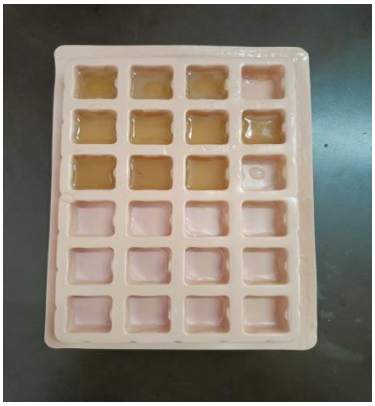


Fig.21: Gummies In mould

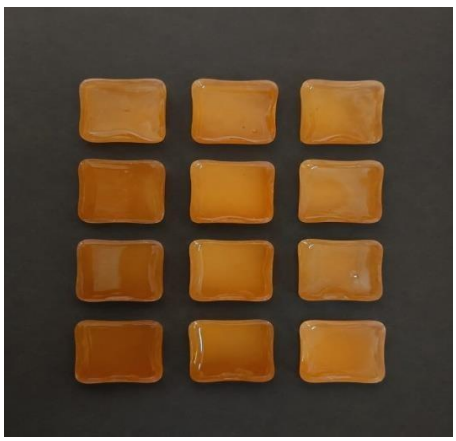


Fig.22: Gummies Formulation

EVALUATION PARAMETERS :- [39-48]

1. Organoleptic Evaluation (Macroscopic Properties)

Table 3

Parameter	F1	F2	F3
Colour	Light orange	Light orange	Light orange
Odour	Pleasant	Pleasant	Pleasant
Taste	Sweet, slightly acidic	Sweet, balanced	Slightly less sweet
Shape	Uniform	Uniform	Uniform
Surface	Smooth	Smooth & glossy	Slightly sticky

Discussion:

- All formulations acceptable
- F3 slightly sticky due to **higher moisture + lower gelatin**

2. Weight Variation Test

Twenty units from each formulation were randomly selected and individually weighed using a calibrated digital balance. The average weight was calculated, and individual weights were compared with the mean to determine uniformity.

Fig.23: Weight Variation

Table 4

Formulation	Average Weight (g)	Range (g)
F1	3.10	3.02- 3.18
F2	3.40	3.32- 3.48
F3	2.90	2.82- 2.98

Discussion:

- Uniform filling confirmed
- Slight variation due to **viscosity differences during pouring**]

3. pH Determination

A specified quantity of the formulation was dissolved in distilled water and allowed to equilibrate. The pH of the resulting solution was measured using a calibrated digital pH meter at room temperature.

Fig.24: Ph Determination

Table 5

Formulation	pH
F1	3.5
F2	4.0
F3	3.3

Discussion:

- Due to **citric acid (0.3 g)**
- Suitable for:
    - Taste masking
    - KI stability

4. Moisture Content (%)

A known weight of the sample was accurately weighed and placed in desiccator containing a suitable desiccant (such as silica gel). The sample was kept for a specified period until a constant weight was obtained. The final weight was recorded. The loss in weight was calculated as percentage moisture content.

The desiccator method was employed to ensure gentle moisture removal and to prevent thermal degradation of the formulation

Table 6.

Formulation	Moisture (%)
F1	16.2 %
F2	14.2 %
F3	18.5 %

Fig.25: Moisture Contain

Discussion:-

- F2 best → **balanced gelatin (8 g) + agar (6 g)**
- F3 high moisture → soft & sticky
- F1 moderate

5. Texture Analysis (Based on Gelatin–Agar Ratio)

Table 7

Formulation	Observation
F1	Soft and elastic
F2	Firm, ideal chewiness
F3	Very soft, less firm

Discussion:

- Texture depends on:
  - Gelatin → elasticity
  - Agar → firmness
- F2 optimized ratio → best structure

6. Content Uniformity (%) (Potassium Iodide)

Table 8

Formulation	Drug Content (%)
F1	96.8 %
F2	99.0 %
F3	95.2 %

Discussion:

- All within **IP/BP limits (85–115%)**
- F2 highest → **better mixing at optimal viscosity**

7. Disintegration / Chewing Time

- Gummies soften, not disintegrate
- F2 → best chew resistance
- F3 → too soft (fast breakdown)

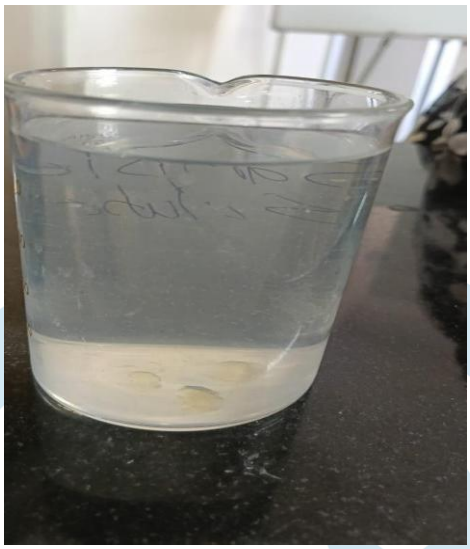


Fig.26 Disintegration Time

Table 9

Formulation	Time
F1	6.2 min
F2	8.0 min
F3	5.5 min

Discussion:-

- Gummies soften , Not disintegrate
- F2 – best chewable resistance
- F3 – too soft (fast breakdown)

8. Stability Study (Based on Your Method)

Table 10

Parameter	F1	F2	F3
Colour change	No	No	No
Odour change	No	No	No
Texture	Slight softening	Stable	Soft
Drug content retained	97%	98–99%	95%

Conditions:

- 25°C ± 2°C
- 60% RH
- 30 days

Discussion:

- F2 most stable
- **F3 affected due to** higher moisture

9. Thickness Test (Diameter/Thickness Uniformity) Method:

The thickness of the prepared gummies was measured using a **digital Vernier caliper**.

- 5 gummies from each formulation were selected randomly
- Thickness was measured at the **center of each gummy**
- Mean thickness was calculated

Fig.27:- Digital Vernier Caliper

Result:

Table 11

Formulation	Thickness (mm)	Range (mm)
F1	8.2 mm	8.0 - 8.4
F2	8.5 mm	8.3 – 8.7
F3	7.8 mm	7.6 – 8.0

Discussion:

- All formulations showed **uniform thickness**, indicating:
  - Proper mould filling
  - Consistent viscosity during pouring
- **F2 showed slightly higher thickness** due to:
  - Higher gelatin (8 g) + agar (6 g)
  - Increased structural strength
- **F3 showed lower thickness** because:
  - Lower gelling agent concentration
  - Higher moisture → slight shrinkage after drying

"Thickness analysis revealed uniform dimensional characteristics among all formulations, with F2 exhibiting slightly higher thickness due to increased gelling agent concentration, indicating better structural integrity and consistency."

RESULT :-

The results of the present study demonstrated the successful formulation and evaluation of potassium iodide-loaded pharmaceutical gummies as a novel dosage form for iodine supplementation. Three formulations (F1, F2, and F3) were prepared using different concentrations of gelatin and agar-agar and evaluated for various physicochemical and quality control parameters. Organoleptic evaluation showed that all formulations possessed acceptable colour, pleasant odour, and good taste. Among all formulations, F2 exhibited the best appearance with a smooth and glossy surface, while F3 showed slight stickiness due to higher moisture content and lower concentration of gelling agents. Weight variation and thickness studies confirmed uniform mould filling and consistent dimensional characteristics in all formulations, indicating proper manufacturing methodology and good formulation reproducibility.

Based on the comparative evaluation of all three formulations (F1 to F3), formulation F2 emerged as the optimized formulation.

It demonstrated :-

- Balanced pH (4.0), suitable for potassium iodide stability and taste masking.
- Excellent texture with ideal firmness and chewiness.
- Smooth and glossy appearance with pleasant taste and odour.
- Lower moisture content (14.2%), reducing stickiness and improving stability.
- Highest drug content uniformity (99.0%), ensuring accurate dosing.

- Better chewing resistance and gradual softening behavior.
- Good dimensional uniformity with proper thickness and structural integrity.
- Excellent stability over 30 days without significant changes in physical properties or drug content.

Thus, the developed potassium iodide gummies can be considered a promising novel drug delivery system for improving iodine supplementation, patient compliance, and prevention of iodine deficiency disorders, especially in pediatric and geriatric populations.

DISCUSSION :-

The present study successfully demonstrated the formulation and evaluation of potassium iodide medicated gummies as a novel dosage form for iodine supplementation. Three formulations (F1, F2, and F3) were prepared using different concentrations of gelatin and agar-agar and evaluated for various physicochemical parameters. All formulations showed acceptable organoleptic properties, including pleasant taste, attractive appearance, and uniform shape. The use of sweetening and flavouring agents effectively masked the unpleasant taste and odour of potassium iodide, thereby improving palatability and patient acceptability. The prepared gummies also exhibited suitable pH, uniform weight variation, and acceptable thickness, indicating proper formulation design and consistent manufacturing process.

Among all formulations, F2 showed superior performance in terms of texture, moisture content, drug content uniformity, and stability. The optimized concentration of gelatin and agar-agar in F2 produced gummies with ideal firmness, elasticity, and chewiness. Lower moisture content in F2 reduced stickiness and contributed to better structural integrity and shelf stability. Content uniformity studies confirmed uniform distribution of potassium iodide throughout the gummy matrix, while stability studies demonstrated that F2 remained stable without significant changes in colour , odour , texture, or drug content during storage. In contrast, F3 showed slight softness and stickiness due to higher moisture content and lower gelling agent concentration.

Overall, the findings of the study indicate that potassium iodide medicated gummies can serve as a promising and patient-friendly alternative to conventional dosage forms for iodine supplementation. The optimized formulation (F2) exhibited excellent physicochemical characteristics, improved stability, and better patient acceptability, making it suitable for pediatric and geriatric populations who often experience difficulty swallowing tablets or capsules. Therefore, the developed gummies have significant potential in improving patient compliance and helping in the prevention and management of iodine deficiency disorders.

CONCLUSION:-

The present study successfully demonstrated the formulation and evaluation of potassium iodide medicated gummies as a novel and patient-friendly dosage form for iodine supplementation. The prepared gummies showed satisfactory physicochemical characteristics, acceptable stability, and improved palatability, making them suitable for effective management and prevention of iodine deficiency disorders.

Among the three formulations prepared, formulation F2 was found to be the optimized formulation based on its superior texture, lower moisture content, excellent drug content uniformity, better chewiness, and improved stability profile. The balanced concentration of gelatin and agar-agar in F2 provided ideal firmness, elasticity, and structural integrity, while maintaining patient acceptability.

The study also confirmed that pharmaceutical gummies can overcome several limitations associated with conventional dosage forms such as tablets and capsules, particularly swallowing difficulties and poor patient compliance in pediatric and geriatric populations. Therefore, potassium iodide medicated gummies represent a promising novel drug delivery system that may improve iodine supplementation and contribute effectively toward the prevention of iodine deficiency disorders.

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